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(71) Applicant: **Matsushita Electric Industrial Co., Ltd.**  
**Kadoma-shi, Osaka 571-8501 (JP)**

(72) Inventors:  
• **MIYOSHI, Koji**  
**Iyomishima-shi, Ehime 799-0432 (JP)**  
• **AGA, Masahiro**  
**Onsen-gun, Ehime 791-0204 (JP)**  
• **SHIGEMATSU, Kaoru**  
**Onsen-gun, Ehime 791-0301 (JP)**

(74) Representative: **Holmes, Miles et al**  
**Novagraaf International S.A.**  
**25, avenue du Paillly**  
**1220 Les Avanchets, Geneva (CH)**

(54) **DEVICE FOR CHROMATOGRAPHIC QUANTITATIVE MEASUREMENT**

(57) In a chromatography quantitative measuring apparatus according to the present invention, a beam applied from a light source (201) to a chromatography test strip (8) is formed into an elliptical shape by an optical means such as a cylindrical lens (205), a variation in absorbance that accompanies elution of a marker reagent is detected while the elliptical beam is applied between a marker reagent hold part (82) and a detection part (83), and a measurement is automatically started in a prescribed period of time since the detection of variation.

According to the chromatography quantitative measuring apparatus so configured, non-uniform coloration is reduced by shaping the beam elliptically with the optical means, whereby the accuracy of quantitative analysis is enhanced, and further the apparatus can be operated easily.

Fig.7 (a)

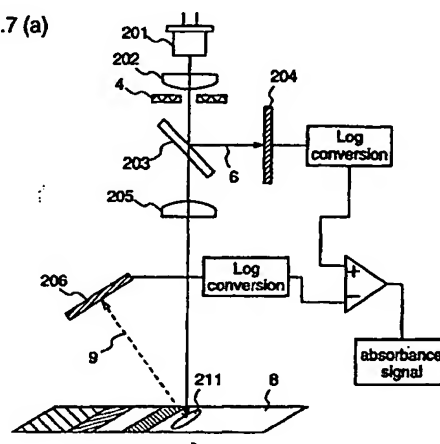
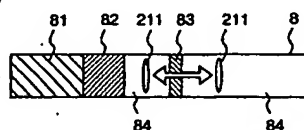


Fig.7 (b)



## Description

## TECHNICAL FIELD

[0001] The present invention relates to a chromatography quantitative measuring apparatus which performs a measurement employing an immuno-chromatography test strip or the like and, more particularly, to one which is improved in performance of a quantitative measurement.

## BACKGROUND ART

[0002] Hereinafter, a description will be given of a spectrophotometer as a conventional chromatography quantitative measuring apparatus. Figure 25(a) is a diagram schematically illustrating the configuration of the conventional reflective spectrophotometer, and figure 25(b) is a diagram illustrating the constitution of a chromatography test strip.

[0003] In figure 25(a), an optical beam 11 emitted from a lamp 1 is input to a diffraction grating 3 via a reflector 2. The optical beam 11 input to the diffraction grating 3 is selected thereby for its light wavelength, and the optical beam 11 is narrowed by an aperture 4 and input to a glass plate 5. The optical beam 11 reflected at the glass plate 5 is received by a first photomultiplier tube 7 as a reference beam 6. On the other hand, the optical beam 11 transmitted through the glass plate 5 is applied to a part of a chromatography test strip 8, and a scattering light 9 from the chromatography test strip 8 is received by a second photomultiplier tube 10. Output signals from the first photomultiplier tube 7 and the second photomultiplier tube 10 are respectively subjected to Log transformation, and a value obtained by subtracting a Log transformed value for the second photomultiplier tube 10 from a Log transformed value for the first photomultiplier tube 7 is output as an absorbance signal.

[0004] As shown in figure 25(b), the immuno-chromatography test strip 8 utilizing an antigen antibody reaction comprises an application part 81 where a liquid sample as an inspection target solution is applied, a marker reagent hold part 82 which holds a marker reagent which is moved by permeation of the liquid sample and has a substance that is specifically bounded to an analysis target included in the liquid which flows therein, a detection part 83 where the marker reagent and the analysis target are bounded and immobilized, a part for absorbing the sample which flows therein, and a remaining base part 84.

[0005] An operation of the so-configured chromatography quantitative measuring apparatus will be described.

[0006] First, when an inspection target solution is applied to the application part 81, the inspection target solution is developed on a development layer 85. At this time, when the inspection target solution reaches the marker reagent hold part 82, a marker reagent is eluted

and specifically bonded to an analysis target included in the inspection target solution. Then, this bounded material is immobilized at the detection part 83, and a non-immobilized residual marker reagent flows downstream of the development layer 85 without being immobilized.

[0007] Next, as shown in figure 25(a), a beam is applied to the chromatography test strip 8 from the light source 1 so as to measure the concentration of the analysis target included in the inspection target solution. There is previously calculated a calibration curve indicating a relationship between the difference between the absorbance signal at the base part 84 of the chromatography test strip 8 and the absorbance signal at the detection part 83, and the concentration of a sample to be measured. The concentration of the sample is calculated by detecting the difference between the absorbance signal at the base part 84 and that at the detection part 83.

[0008] While analysis by immuno-chromatography is generally qualitative, a method of quantitative analysis has been also developed. For example, Japanese Published Patent Application No. Hei.8-240591 discloses a method by which the degree of coloration is quantitatively measured by measuring signals of absorbance, reflection, and the like at a coloration part on a test strip employing a spectrophotometer after a sample is applied to the immuno-chromatography test strip and a reaction is caused thereon. Further, Japanese Published Patent Application No. Hei.11-142338 discloses a method by which the absorbance at the coloration part is measured without influence of outside light by using a light emitting diode as a light source.

[0009] However, in the conventional chromatography quantitative measuring apparatus, which has no problem with respect to immuno-chromatography for qualitative analysis, in case of quantitative analysis, when for example a liquid sample including cellular components, such as blood, is to be analyzed, the viscosity of the liquid sample or the existence of cellular components generates partial clogging, resulting in non-uniform coloration at the base part of the immuno-chromatography test strip. Thus, as the concentration is obtained by the difference between the absorbance signal at the base part and that at the detection part, when an error is generated due to the non-uniform coloration at the base part according to the position where a beam is applied, a quantitative measurement is disturbed. Further, when a spectrophotometer which uses a lamp as a light source is used, it is difficult to reduce the size and cost of the apparatus.

[0010] Further, in the above-described conventional chromatography quantitative measuring apparatus, since the inspection target solution is slowly developed on the development layer 85, a value of a detection signal is gradually varied with time at the detection part 83 of the chromatography test strip 8. That is, in order to obtain a more stable measurement result, it is important to manage time to perform a measurement. In the con-

ventional measurement using a spectrophotometer, there is no function of managing time, so that an inspector has to manage time manually, resulting in a trouble in a measurement operation. Further, there is sometimes a test strip on which a normal measurement is disturbed according to the inspection-target solution or a state of the chromatography test strip 8. In the conventional measurement using a spectrophotometer, there is no function of detecting the state of the inspection target solution or the chromatography test strip 8, so that an inspector has to judge the state manually, resulting in a trouble in a measurement operation. Furthermore, since a marker reagent remains at the marker reagent hold part 82 of the chromatography test strip 8 even after its elution, influences of the residual marker reagent must be reduced in order to enhance the accuracy of a quantitative measurement. However, in the conventional measurement using a spectrophotometer, there is no function of recognizing the residual marker reagent, so that an inspector has to recognize it manually, resulting in a trouble in a measurement operation.

[0011] Further, an immuno-chromatography test strip for a qualitative or semi-quantitative measurement is generally put in a hollow casing and discarded together with the casing when an inspection is ended. For example, in Japanese Published Patent Applications No. Hei. 1-503174 and No. Hei.6-180320, there are disclosed methods in which a casing 90 with an injection part 91 through which a liquid sample is applied to the immuno-chromatography test strip, and an aperture 92 for observing a coloration part are provided, and the degree of coloration is visually judged as an inspection result, as shown in figure 25(c). Further, in immuno-chromatography quantitative analysis for measuring the degree of coloration by a multi-purpose spectrophotometer, there is no problem in employing the casing when the frequency of measurements is low. However, when a quantitative measurement is performed frequently for the purpose of clinical examination or the like, there is a problem of the cost of the casing and a storage space to be secured. On the other hand, when the quantitative measurement is performed by solely employing the immuno-chromatography test strip without the casing, the test strip is put on a measurement table of the spectrophotometer directly, so that a sample adheres to a measuring apparatus. Furthermore, the test strip must be attached to the measuring apparatus precisely so that a beam is accurately applied to the base part and the detection part.

[0012] The present invention is made to solve the above-mentioned problems and has for its object to provide a chromatography quantitative measuring apparatus which makes highly accurate immuno-chromatography quantitative analysis possible, as well as realizes a reduction in the size and cost of the apparatus, a chromatography quantitative measuring apparatus which improves operability thereof, or a chromatography quantitative measuring apparatus which enhances the

accuracy of a quantitative measurement.

## DISCLOSURE OF THE INVENTION

5 [0013] According to Claim 1 of the present invention, there is provided a chromatography quantitative measuring apparatus which applies a beam emitted from a light source to a sample, detects an optical signal from a transmitted light or reflected light from the sample, and quantitatively reads the concentration of the sample from the signal, including: an optical means for forming the beam emitted from the light source into an elliptical or rectangular shape and applying the elliptically or rectangularly shaped beam to the sample.

10 [0014] Therefore, it is possible to perform a quantitative measurement with fewer measurement errors which are caused by non-uniform coloration at a base part.

15 [0015] According to Claim 2 of the present invention, in the chromatography quantitative measuring apparatus as defined in Claim 1, the sample is put on an immuno-chromatography test strip, and the beam applied to the sample has a longer side which is shorter than the width of the immuno-chromatography test strip in the width direction that is orthogonal with respect to the long-side direction.

20 [0016] Therefore, it is possible to perform a quantitative measurement with much fewer measurement errors which are caused by non-uniform coloration at a base part.

25 [0017] According to Claim 3 of the present invention, in the chromatography quantitative measuring apparatus as defined in Claim 1, the sample is put on an immuno-chromatography test strip, and the beam applied to the sample has a shorter side which is shorter than the width of a detection part region of the immuno-chromatography test strip.

30 [0018] Therefore, it is possible to perform a quantitative measurement with much fewer measurement errors which are caused by non-uniform coloration at a base part.

35 [0019] According to Claim 4 of the present invention, in the chromatography quantitative measuring apparatus as defined in any of Claims 1 to 3, the optical signal is detected by scanning the beam applied to the sample, or the sample.

40 [0020] Therefore, an operation for measuring a difference between absorbance signals is simplified, resulting in an effective measurement.

45 [0021] According to Claim 5 of the present invention, in the chromatography quantitative measuring apparatus as defined in Claim 1, a laser is used as the light source, and a laser beam from the light source is converted into a collimated beam via a collimator lens, and the optical means forms the collimated beam into an elliptical shape via a cylindrical lens and applies the elliptically shaped beam to the sample.

50 [0022] Therefore, the size of the apparatus can be re-

duced by employing a laser as a light source, and since a measurement is sufficiently performed with a photodiode, as compared with a conventional sample concentration measuring apparatus which uses a photomultiplier tube to receive a scattering light and a reflected light from a sample, the cost of the apparatus can be reduced.

[0023] According to Claim 6 of the present invention, in the chromatography quantitative measuring apparatus as defined in Claim 1, a laser is used as the light source, and the laser beam from the light source is converted into a collimated beam via a collimator lens, and the optical means forms the collimated beam into a rectangular shape via a rectangularly shaped aperture member and applies the rectangularly shaped beam to the sample. Therefore, the size of the apparatus can be reduced by employing a laser as a light source, and since a measurement is sufficiently performed with a photodiode, as compared with a conventional apparatus using a photomultiplier tube to receive a scattering light and a reflected light from a sample, the cost of the apparatus can be reduced.

[0024] According to Claim 7 of the present invention, there is provided a chromatography quantitative measuring apparatus which applies a beam emitted from a light source to a sample, detects an optical signal from a transmitted light or reflected light from the sample, and quantitatively reads the concentration of the sample from the signal, including: a laser as the light source; and a collimator lens which converts the laser beam into a collimated beam, in which chromatography quantitative measuring apparatus when the collimated beam is shaped rectangularly via an aperture member and the rectangularly shaped beam is applied to the sample, the direction of a longer side of the rectangularly shaped beam is made to correspond to the direction in which the beam divergence angle of the laser becomes larger.

[0025] Therefore, it is possible to perform a quantitative measurement with much fewer measurement errors.

[0026] According to Claim 8 of the present invention, there is provided a chromatography quantitative measuring apparatus which applies a beam emitted from a light source to a sample, detects an optical signal from a transmitted light or reflected light from the sample, and quantitatively reads the concentration of the sample from the signal, including: a laser as the light source; and a collimator lens which converts the laser beam into a collimated beam, in which chromatography quantitative measuring apparatus when the collimated beam is shaped elliptically via a cylindrical lens and the elliptically shaped beam is applied to the sample, the direction of a longer side of the elliptically shaped beam is made to correspond to the direction in which the beam divergence angle of the laser becomes larger.

[0027] Therefore, it is possible to perform a quantitative measurement with much fewer measurement errors.

[0028] According to Claim 9 of the present invention, the chromatography quantitative measuring apparatus as defined in any of Claims 5 to 8, includes: a compensation means for storing the initial wavelength of the laser, calculating the present wavelength of the laser to compensate by provision of a temperature detection element in the vicinity of the laser, and compensating an optical signal detection value or the converted concentration of the sample which is obtained by converting the optical signal detection value.

[0029] Therefore, it is possible to perform a quantitative measurement with fewer measurement errors by reducing an influence of hardware configuration or usage environment.

[0030] According to Claim 10 of the present invention, in the chromatography quantitative measuring apparatus as defined in Claim 9, the compensation means performs processing for detecting the optical signal, processing for obtaining the converted concentration of the sample, and processing for compensating the converted concentration, with the same calculator.

[0031] Therefore, it is possible to reduce the size of the apparatus.

[0032] According to Claim 11 of the present invention, in the chromatography quantitative measuring apparatus as defined in any of Claims 5 to 8, the concentration of the sample is calculated from a difference between electronic signals obtained by two light receiving elements, i.e., a reference beam light receiving element which receives a reference beam separated from the beam emitted from the laser, and a scattering light receiving element which receives a scattering light generated by the application of the laser to the sample, and the area of the reference beam light receiving element for receiving light is smaller than the area of the scattering light receiving element for receiving light.

[0033] Therefore, it is possible to reduce the cost and size of the apparatus.

[0034] According to Claim 12 of the present invention, in the chromatography quantitative measuring apparatus as defined in any of Claims 5 to 8, the concentration of the sample is calculated from a difference between electronic signals obtained by two light receiving elements, i.e., a reference beam light receiving element which receives a reference beam separated from the beam emitted from the laser, and a scattering light receiving element which receives a scattering light generated by the application of the laser to the sample, and this chromatography quantitative measuring apparatus includes: a condensing means for condensing the scattering light from the sample on the scattering light receiving element.

[0035] Therefore, it is possible to reduce the size of the scattering light receiving element, thereby reducing the cost and size of the apparatus.

[0036] According to Claim 13 of the present invention, in the chromatography quantitative measuring apparatus as defined in Claim 12, the condensing means is a

concave mirror which condenses a light from the sample that is scattered in the opposite direction of the direction in which the scattering light receiving element is arranged, on the scattering light receiving element.

[0037] Therefore, it is possible to reduce the size of the scattering light receiving element, thereby reducing the cost of the apparatus.

[0038] According to Claim 14 of the present invention, in the chromatography quantitative measuring apparatus as defined in Claim 12, the condensing means is a condensing lens arranged between the sample and the scattering light receiving element, which condenses the scattering light from the sample that goes toward the scattering light receiving element, on the scattering light receiving element.

[0039] Therefore, it is possible to reduce the size of the scattering light receiving element, thereby reducing the cost of the apparatus.

[0040] According to Claim 15 of the present invention, there is provided a chromatography quantitative measuring apparatus which applies an optical beam emitted from a light source to a chromatography test strip that comprises an application part where an inspection target solution is applied; a marker reagent hold part which holds a marker reagent that can be eluted by development of the inspection target solution; a base part where a specific binding reaction is caused between the marker reagent and an analysis target included in the inspection target solution; and a detection part where a bounded material of the marker reagent and the analysis target is immobilized, detects an optical signal utilizing a transmitted light or reflected light from the chromatography test strip, and quantitatively measures the concentration of the analysis target included in the inspection target solution from the signal, in which chromatography quantitative measuring apparatus the inspection target solution is applied to the chromatography test strip, the optical beam is applied to a prescribed position of the base part, a variation of the transmitted light or reflected light from the chromatography test strip, which is generated by the elution of the marker reagent that accompanies the development of the inspection target solution, is detected, and the concentration of the analysis target included in the inspection target solution is measured in a prescribed period of time since the detection of variation.

[0041] Therefore, an operator does not need to manage time manually, and because a measurement is performed after the elution of the marker reagent is detected, it is possible to discriminate a used test strip where a marker reagent is already eluted.

[0042] According to Claim 16 of the present invention, in the chromatography quantitative measuring apparatus as defined in Claim 15, at least one of temperature and humidity is monitored, and a previously set prescribed period of time after which the measurement of the concentration of the analysis target is performed is compensated.

[0043] Therefore, it is possible to reduce influence of surrounding temperature and humidity on a variation in speed of development of the inspection target solution on the chromatography test strip.

[0044] According to Claim 17 of the present invention, in the chromatography quantitative measuring apparatus as defined in Claim 15, the light source is repeatedly lighted and extinguished alternately while the development of the inspection target solution is detected.

[0045] Therefore, it is possible to prevent deterioration in performance of the chromatography test strip, which accompanies temperature rise at a part for applying a laser beam to the chromatography test strip.

[0046] According to Claim 18 of the present invention, in the chromatography quantitative measuring apparatus as defined in Claim 15, the light source is extinguished until shortly before the detection of the development of the inspection target solution.

[0047] Therefore, it is possible to prevent deterioration in performance of the chromatography test strip, which accompanies temperature rise at a part for applying a laser beam to the chromatography test strip.

[0048] According to Claim 19 of the present invention, in the chromatography quantitative measuring apparatus as defined in Claim 15, output from the light source is set lower than that when the concentration of the analysis target is measured, while the development of the inspection target solution is detected.

[0049] Therefore, it is possible to prevent deterioration in performance of the chromatography test strip, which accompanies temperature rise at a part for applying a laser beam to the chromatography test strip.

[0050] According to Claim 20 of the present invention, there is provided a chromatography quantitative measuring apparatus which applies an optical beam emitted from a light source to a chromatography test strip that comprises an application part where an inspection target solution is applied; a marker reagent hold part which holds a marker reagent that can be eluted by development of the inspection target solution; a base part where a specific binding reaction is caused between the marker reagent and an analysis target included in the inspection target solution; and a detection part where a bounded material of the marker reagent and the analysis target is immobilized, detects an optical signal utilizing a transmitted light or reflected light from the chromatography test strip, and quantitatively measures the concentration of the analysis target included in the inspection target solution from the signal, in which chromatography quantitative measuring apparatus the inspection target solution is applied to the chromatography test strip, a speed of development after the application of the inspection target solution is detected, and it is judged whether performance of the chromatography test strip is high or low from the speed of development.

[0051] Therefore, it is possible to judge whether there is a defect on the chromatography test strip such as abnormal clogging.

[0052] According to Claim 21 of the present invention, in the chromatography quantitative measuring apparatus as defined in Claim 20, the speed of development is calculated by detecting time variation of value of a detection signal, which is generated by the flow of the marker reagent that accompanies the development of the inspection target solution on the chromatography test strip.

[0053] Therefore, it is possible to judge whether there is a defect on the chromatography test strip such as abnormal clogging.

[0054] According to Claim 22 of the present invention, in the chromatography quantitative measuring apparatus as defined in Claim 20, the speed of development is calculated from a speed of scanning of the optical beam, when the optical beam is scanned so that a value of the detection signal, which is generated by the elution of the marker reagent that accompanies the development of the inspection target solution on the chromatography test strip, is kept constant.

[0055] Therefore, it is possible to judge whether there is a defect on the chromatography test strip such as abnormal clogging.

[0056] According to Claim 23 of the present invention, in the chromatography quantitative measuring apparatus as defined in Claim 20, a discrimination value of the speed of development, from which whether performance of the chromatography test strip is high or low is judged, is compensated from a result of measuring at least one of surrounding temperature and humidity at the development of the inspection target solution on the chromatography test strip.

[0057] Therefore, it is possible to prevent an erroneous judgement as to whether performance is high or low, which is due to influence of temperature or humidity.

[0058] According to Claim 24 of the present invention, there is provided a chromatography quantitative measuring apparatus which applies an optical beam emitted from a light source to a chromatography test strip that comprises an application part where an inspection target solution is applied; a marker reagent hold part which holds a marker reagent that can be eluted by development of the inspection target solution; a base part where a specific binding reaction is caused between the marker reagent and an analysis target included in the inspection target solution; and a detection part where a bound material of the marker reagent and the analysis target is immobilized, detects an optical signal utilizing a transmitted light or reflected light from the chromatography test strip, and quantitatively measures the concentration of the analysis target included in the inspection target solution from the signal, in which chromatography quantitative measuring apparatus a kind of inspection target solution is judged from a detection signal at the base part on the chromatography test strip where the inspection target solution is applied.

[0059] Therefore, it is possible to judge a kind of inspection target solution which is applied to the chroma-

tography test strip.

[0060] According to Claim 25 of the present invention, in the chromatography quantitative measuring apparatus as defined in Claim 24, the base part where the detection signal is measured is located downstream of the detection part in the direction of the development.

[0061] Therefore, it is possible to suppress an erroneous judgement on a kind of inspection target solution, which is due to influences of a marker reagent that is liable to remain at a base part upstream of the detection part as compared with a base part downstream thereof.

[0062] According to Claim 26 of the present invention, in the chromatography quantitative measuring apparatus as defined in Claim 24, a calibration curve in conformity with the inspection target solution can be selected previously.

[0063] Therefore, when plural kinds of inspection target solutions are measured, an operator does not need to manually input a kind of inspection target solution to the apparatus, resulting in an automatic measurement.

[0064] According to Claim 27 of the present invention, there is provided a chromatography quantitative measuring apparatus which applies an optical beam emitted from a light source to a chromatography test strip that comprises an application part where an inspection target solution is applied; a marker reagent hold part which holds a marker reagent that can be eluted by development of the inspection target solution; a base part where a specific binding reaction is caused between the marker reagent and an analysis target included in the inspection target solution; and a detection part where a bound material of the marker reagent and the analysis target is immobilized, detects an optical signal utilizing a transmitted light or reflected light from the chromatography test strip, and quantitatively measures the concentration of the analysis target included in the inspection target solution from the signal, in which chromatography quantitative measuring apparatus deficiency in the amount of inspection target solution applied and insufficient development on the chromatography test strip are judged from a detection signal that is obtained by applying the optical beam to the downstream end part of the base part on the chromatography test strip where the inspection target solution is applied.

[0065] Therefore, it is possible to detect deficiency in the amount of inspection target solution applied to the chromatography test strip, or insufficient development on the chromatography test strip which is generated by clogging or the like.

[0066] According to Claim 28 of the present invention, in the chromatography quantitative measuring apparatus as defined in Claim 27, the optical beam is scanned from the upstream end part of the base part on the chromatography test strip to the downstream end part thereof.

[0067] Therefore, no new light source is required to detect deficiency in the amount of inspection target solution applied and insufficient development on the chroma-

matography test strip, thereby restraining increase in the size and cost of the apparatus that accompany addition of the function.

[0068] According to Claim 29 of the present invention, there is provided a chromatography quantitative measuring apparatus which applies an optical beam emitted from a light source to a chromatography test strip that comprises an application part where an inspection target solution is applied; a marker reagent hold part which holds a marker reagent that can be eluted by development of the inspection target solution; a base part where a specific binding reaction is caused between the marker reagent and an analysis target included in the inspection target solution; and a detection part where a bounded material of the marker reagent and the analysis target is immobilized, detects an optical signal utilizing a transmitted light or reflected light from the chromatography test strip, and quantitatively measures the concentration of the analysis target included in the inspection target solution from the signal, in which chromatography quantitative measuring apparatus when a detection signal at a part downstream of the detection part in the direction of the development, where influence of the detection part is not exerted, is a standard value, a detection signal at the detection part is taken as a detection signal for the measurement of concentration.

[0069] Therefore, it is possible to suppress influence of an error in a measurement of absorbance, which is due to a marker reagent liable to remain at a base part upstream of the detection part as compared with a base part downstream thereof.

[0070] According to Claim 30 of the present invention, in the chromatography quantitative measuring apparatus as defined in Claim 29, the detection signal for the measurement of concentration is an average value of values about an extreme value of the detection part, and the detection signal as the standard value is an average value of values in the vicinity of the position downstream of the detection part in the direction in which the inspection target solution is developed, where influence of the detection part is not exerted.

[0071] Therefore, even when an electrical noise is accidentally added to the detection signal, it is possible to reduce influence on the result of calculation for obtaining the concentration of an analysis target.

[0072] According to Claim 31 of the present invention, in the chromatography quantitative measuring apparatus as defined in Claim 29, the detection signal for the measurement of concentration is an intermediate value of values about an extreme value of the detection part, and the detection signal as the standard value is an intermediate value of values in the vicinity of the position downstream of the detection part in the direction in which the inspection target solution is developed, where influence of the detection part is not exerted.

[0073] Therefore, even when an electrical noise is accidentally added to the detection signal, influence on the result of calculation for obtaining the concentration of an

analysis target can be reduced further as compared with a case when an average value is employed.

[0074] According to Claim 32 of the present invention, in the chromatography quantitative measuring apparatus as defined in Claim 29, a comparison is made of values about an extreme value of the detection signal at the detection part, and when a difference therebetween exceeds a discrimination value, the chromatography test strip is judged to be low in performance.

[0075] Therefore, it is possible to avoid an erroneous measurement due to non-uniform immobilization of a marker reagent at the detection part, a flaw on the surface of the chromatography test strip, or the like.

[0076] According to Claim 33 of the present invention, in the chromatography quantitative measuring apparatus as defined in Claim 29, a comparison is made of values in the vicinity of a position downstream of the detection part in the direction of the development, where influence of the detection part is not exerted, and when a difference therebetween exceeds a discrimination value, the chromatography test strip is judged to be low in performance.

[0077] Therefore, it is possible to avoid an erroneous measurement due to non-uniform development of the inspection target solution at the base part by clogging, a flaw on the surface of the chromatography test strip, or the like.

[0078] According to Claim 34 of the present invention, there is provided a chromatography quantitative measuring apparatus which applies an optical beam emitted from a light source to a chromatography test strip that comprises an application part where an inspection target solution is applied; a marker reagent hold part which holds a marker reagent that can be eluted by development of the inspection target solution; a base part where a specific binding reaction is caused between the marker reagent and an analysis target included in the inspection target solution; and a detection part where a bounded material of the marker reagent and the analysis target is immobilized, detects an optical signal utilizing a transmitted light or reflected light from the chromatography test strip, and quantitatively measures the concentration of the analysis target included in the inspection target solution from the signal, in which chromatography quantitative measuring apparatus the measurement of concentration is performed on the chromatography test strip exclusive of the marker reagent hold part.

[0079] Therefore, a measured value of absorbance at the marker reagent hold part is not included, whereby an erroneous recognition of the peak position of the absorbance is prevented, resulting in a normal detection of the concentration of an analysis target.

[0080] According to Claim 35 of the present invention, there is provided a chromatography quantitative measuring apparatus which applies an optical beam emitted from a light source to a chromatography test strip that comprises an application part where an inspection target solution is applied; a marker reagent hold part which



holds a marker reagent that can be eluted by development of the inspection target solution; a base part where a specific binding reaction is caused between the marker reagent and an analysis target included in the inspection target solution; and a detection part where a bound material of the marker reagent and the analysis target is immobilized, detects an optical signal utilizing a transmitted light or reflected light from the chromatography test strip, and quantitatively measures the concentration of the analysis target included in the inspection target solution from the signal, in which chromatography quantitative measuring apparatus a region on the chromatography test strip where a value of the detection signal is flat is taken as a region of the marker reagent hold part.

[0081] Therefore, an erroneous recognition of the peak position of the absorbance is prevented, resulting in a normal detection of the concentration of an analysis target.

[0082] According to Claim 36 of the present invention, in the chromatography quantitative measuring apparatus as defined in Claim 35, the width of the region on the chromatography test strip where the value of the detection signal is flat is calculated, and the width is compared with a prescribed width of the marker reagent hold part.

[0083] Therefore, the amount of marker reagent held can be confirmed, whereby it is possible to judge whether the chromatography test strip is low in performance.

[0084] According to Claim 37 of the present invention, in the chromatography quantitative measuring apparatus as defined in Claim 35, a value in the region on the chromatography test strip where the detection signal is flat is detected, and the amount of residual marker reagent is confirmed from the detected value.

[0085] Therefore, it is possible to confirm whether the marker reagent has flown normally or not.

[0086] According to Claim 38 of the present invention, there is provided a chromatography quantitative measuring apparatus which applies an optical beam emitted from a light source to a chromatography test strip that comprises an application part where an inspection target solution is applied; a marker reagent hold part which holds a marker reagent that can be eluted by development of the inspection target solution; a base part where a specific binding reaction is caused between the marker reagent and an analysis target included in the inspection target solution; and a detection part where a bound material of the marker reagent and the analysis target is immobilized, detects an optical signal utilizing a transmitted light or reflected light from the chromatography test strip, and quantitatively measures the concentration of the analysis target included in the inspection target solution from the signal, in which chromatography quantitative measuring apparatus a rise and fall of a detection signal are recognized, and an extreme value of the detection signal is obtained.

[0087] Therefore, an erroneous recognition of the peak position of the absorbance is prevented, resulting

in a normal detection of the concentration of an analysis target.

[0088] According to Claim 39 of the present invention, in the chromatography quantitative measuring apparatus as defined in Claim 38, the rise and fall of the detection signal is recognized, an interval between the rise and the fall is calculated, and the size of the interval is compared with a prescribed width of the detection part.

[0089] Therefore, the width of the detection part can be confirmed, whereby it is possible to judge whether the chromatography test strip is low in performance.

[0090] According to Claim 40 of the present invention, there is provided a chromatography quantitative measuring apparatus for performing a quantitative measurement by applying an inspection target solution to an immuno-chromatography test strip, applying a beam to a detection part of the immuno-chromatography test strip after development of the inspection target solution, so as to detect an optical signal, and quantitatively reading the concentration of a sample from the detected signal, which chromatography quantitative measuring apparatus includes: a fixing table for holding the immuno-chromatography test strip and a measurement table for holding the fixing table, in which the immuno-chromatography test strip comprises a development layer for developing the inspection target solution and a carrier for holding the development layer.

[0091] Therefore, the immuno-chromatography test strip can be accurately attached to the chromatography quantitative measuring apparatus, and it is possible to reduce the cost for a casing and a storage space.

[0092] According to Claim 41 of the present invention, in the chromatography quantitative measuring apparatus as defined in Claim 40, the measurement table is provided with a groove for positioning the fixing table.

[0093] Therefore, the fixing table can be accurately attached to the measurement table.

[0094] According to Claim 42 of the present invention, in the chromatography quantitative measuring apparatus as defined in Claim 40, the measurement table is provided with a movable projection for fixing the fixing table.

[0095] Therefore, the fixing table can be accurately attached to the measurement table.

[0096] According to Claim 43 of the present invention, in the chromatography quantitative measuring apparatus as defined in Claim 40, the quantitative measurement is performed by scanning the beam.

[0097] Therefore, an absorbance signal at both of the base part and the detection part of the immuno-chromatography test strip can be obtained.

[0098] According to Claim 44 of the present invention, in the chromatography quantitative measuring apparatus as defined in Claim 40, the fixing table is provided with a projection, and the carrier is provided with a hole in which the projection can be inserted.

[0099] Therefore, the immuno-chromatography test strip can be positioned on the fixing table and attached



thereto.

[0100] According to Claim 45 of the present invention, in the chromatography quantitative measuring apparatus as defined in Claim 44, the hole has a round shape.

[0101] Therefore, the immuno-chromatography test strip can be positioned on the fixing table and attached thereto.

[0102] According to Claim 46 of the present invention, in the chromatography quantitative measuring apparatus as defined in Claim 44, the hole has a rectangular shape.

[0103] Therefore, the immuno-chromatography test strip can be positioned on the fixing table and attached thereto.

[0104] According to Claim 47 of the present invention, in the chromatography quantitative measuring apparatus as defined in Claim 44, the hole is provided downstream of the development layer in the direction in which the inspection target solution is developed.

[0105] Therefore, a sample is prevented from adhering to the fixing table.

[0106] According to Claim 48 of the present invention, in the chromatography quantitative measuring apparatus as defined in Claim 44, the hole is provided asymmetrically with respect to the center line of the immuno-chromatography test strip in the longer-side direction.

[0107] Therefore, the immuno-chromatography test strip is prevented from being attached to the fixing table inside out.

[0108] According to Claim 49 of the present invention, in the chromatography quantitative measuring apparatus as defined in Claim 40, the fixing table is provided with a guide, and the carrier is larger than the development layer and follows the shape of the guide.

[0109] Therefore, the immuno-chromatography test strip can be accurately attached to the fixing table without the development layer adhering to the guide.

[0110] According to Claim 50 of the present invention, in the chromatography quantitative measuring apparatus as defined in Claim 49, a part of the guide is inclined.

[0111] Therefore, the carrier can easily follow the shape of the guide.

[0112] According to Claim 51 of the present invention, in the chromatography quantitative measuring apparatus as defined in Claim 49, the carrier is provided with a notch in which the guide can be inserted.

[0113] Therefore, the immuno-chromatography test strip can be accurately attached to the fixing table without the development layer adhering to the guide.

[0114] According to Claim 52 of the present invention, in the chromatography quantitative measuring apparatus as defined in Claim 40, the measurement table is provided with a projection, and the immuno-chromatography test strip and the fixing table are provided with holes in which the projection can be inserted.

[0115] Therefore, the immuno-chromatography test strip can be easily attached to the fixing table, as well as accurately attached to the measurement table.

[0116] According to Claim 53 of the present invention, in the chromatography quantitative measuring apparatus as defined in Claim 52, the projection has its end inclined.

5 [0117] Therefore, the immuno-chromatography test strip can be attached more easily.

[0118] According to Claim 54 of the present invention, the chromatography quantitative measuring apparatus as defined in Claim 40, includes: a test strip fixing device 10 for fixing the immuno-chromatography test strip on the fixing table, in which the test strip fixing device presses the vicinity of a measurement area of the immuno-chromatography test strip.

[0119] Therefore, a part of the immuno-chromatography test strip where a beam is applied can be smoothed.

15 [0120] According to Claim 55 of the present invention, in the chromatography quantitative measuring apparatus as defined in Claim 54, the test strip fixing device presses the carrier of the immuno-chromatography test strip.

20 [0121] Therefore, a part of the immuno-chromatography test strip where a beam is applied can be smoothed without the development layer adhering to the test strip fixing device.

25 [0122] According to Claim 56 of the present invention, in the chromatography quantitative measuring apparatus as defined in Claim 54, the test strip fixing device is provided with a transmission window through which the beam is transmitted.

30 [0123] Therefore, a measurement operation can be performed while the test strip fixing device is attached.

[0124] According to Claim 57 of the present invention, in the chromatography quantitative measuring apparatus as defined in Claim 54, the test strip fixing device is provided with pawl-shaped projections for fixing the test strip fixing device on the fixing table.

[0125] Therefore, the test strip fixing device can be easily attached.

40 [0126] According to Claim 58 of the present invention, in the chromatography quantitative measuring apparatus as defined in Claim 54, the test strip fixing device slides along the fixing table.

[0127] Therefore, the test strip fixing device can be easily attached.

45 [0128] According to Claim 59 of the present invention, in the chromatography quantitative measuring apparatus as defined in Claim 58, the test strip fixing device or the fixing table is provided with an inclination part, and the test strip fixing device and the fixing table are brought into contact at the inclination part, thereby fixing the test strip fixing device on the fixing table.

[0129] Therefore, the test strip fixing device can be easily fixed on the fixing table.

50 [0130] According to Claim 60 of the present invention, in the chromatography quantitative measuring apparatus as defined in Claim 54, the test strip fixing device is integrated with the fixing table.

[0131] Therefore, it is possible to prevent a loss of the

test strip fixing device.

[0132] According to Claim 61 of the present invention, in the chromatography quantitative measuring apparatus as defined in Claim 54, the test strip fixing device is provided with handles.

[0133] Therefore, the test strip fixing device is easy to deal with.

[0134] According to Claim 62 of the present invention, in the chromatography quantitative measuring apparatus as defined in Claim 54, the test strip fixing device is provided with a needle which penetrates the immuno-chromatography test strip.

[0135] Therefore, the immuno-chromatography test strip can be easily removed from the fixing table.

[0136] According to Claim 63 of the present invention, in the chromatography quantitative measuring apparatus as defined in Claim 40, the carrier is provided with grooves, and the fixing table or the measurement table is provided with a guide which can be inserted in the grooves.

[0137] Therefore, the immuno-chromatography test strip can be accurately attached to the fixing table without the development layer adhering to the guide.

[0138] According to Claim 64 of the present invention, in the chromatography quantitative measuring apparatus as defined in Claim 63, the grooves are formed by a laser cutter.

[0139] Therefore, the process of manufacturing the immuno-chromatography test strip can be simplified.

[0140] According to Claim 65 of the present invention, in the chromatography quantitative measuring apparatus as defined in Claim 40, the fixing table is provided with an insertion slot in which the immuno-chromatography test strip can be inserted.

[0141] Therefore, the immuno-chromatography test strip can be easily attached to the fixing table.

[0142] According to Claim 66 of the present invention, in the chromatography quantitative measuring apparatus as defined in Claim 65, the insertion slot is inclined.

[0143] Therefore, the immuno-chromatography test strip can be easily inserted in the fixing table.

[0144] According to Claim 67 of the present invention, in the chromatography quantitative measuring apparatus as defined in Claim 65, the immuno-chromatography test strip is provided with a notch at its end on the side of insertion into the fixing table, and the fixing table is provided with a projection which has the shape same as that of the notch.

[0145] Therefore, the immuno-chromatography test strip can be inserted in the fixing table as well as positioned therein.

[0146] According to Claim 68 of the present invention, in the chromatography quantitative measuring apparatus as defined in Claim 67, the notch is provided asymmetrically with respect to the center line of the immuno-chromatography test strip in the longer-side direction.

[0147] Therefore, it is possible to prevent the immuno-chromatography test strip from being inserted in the fix-

ing table inside out.

[0148] According to Claim 69 of the present invention, in the chromatography quantitative measuring apparatus as defined in Claim 65, the carrier is provided with a groove at its end on the side of insertion of the immuno-chromatography test strip into the fixing table, and the fixing table is provided with a projection which can be inserted in the groove.

[0149] Therefore, the immuno-chromatography test strip can be inserted in the fixing table as well as positioned therein, and further fixed in the fixing table.

[0150] According to Claim 70 of the present invention, the chromatography quantitative measuring apparatus as defined in Claim 69, includes: a means for detecting whether the projection is inserted in the groove.

[0151] Therefore, it is possible to recognize that the immuno-chromatography test strip is correctly disposed in the fixing table.

[0152] According to Claim 71 of the present invention, in the chromatography quantitative measuring apparatus as defined in Claim 65, the immuno-chromatography test strip is shaped to have stages by narrowing the width on the side of insertion into the fixing table. Therefore, the immuno-chromatography test strip can be inserted in the fixing table as well as positioned therein.

[0153] According to Claim 72 of the present invention, in the chromatography quantitative measuring apparatus as defined in Claim 65, the fixing table is provided with an elastic member for pressing the immuno-chromatography test strip.

[0154] Therefore, a part of the immuno-chromatography test strip where a beam is applied can be smoothed.

[0155] According to Claim 73 of the present invention, in the chromatography quantitative measuring apparatus as defined in Claim 72, the elastic member is integrated with the fixing table.

[0156] Therefore, it is possible to prevent a loss of the elastic member.

[0157] According to Claim 74 of the present invention, in the chromatography quantitative measuring apparatus as defined in Claim 72, the elastic member has its end inclined.

[0158] Therefore, the immuno-chromatography test strip can be smoothly inserted in the fixing table.

[0159] According to Claim 75 of the present invention, the chromatography quantitative measuring apparatus as defined in Claim 72, includes: a mechanism for releasing the press by the elastic member.

[0160] Therefore, the immuno-chromatography test strip can be easily removed from the fixing table.

[0161] According to Claim 76 of the present invention, the chromatography quantitative measuring apparatus as defined in Claim 40, includes: an elastic member for pressing the immuno-chromatography test strip.

[0162] Therefore, the immuno-chromatography test strip can be easily attached to the fixing table, and a part where a beam is applied can be smoothed.

[0163] According to Claim 77 of the present invention,

in the chromatography quantitative measuring apparatus as defined in Claim 72 or 76, the elastic member is detachable.

[0164] Therefore, it is possible to promptly cope with a case where the elastic member is defective.

[0165] According to Claim 78 of the present invention, in the chromatography quantitative measuring apparatus as defined in Claim 40, an operator can hold the carrier to detach the immuno-chromatography test strip from the fixing table.

[0166] Therefore, an operator is not contaminated with a sample when detaching the immuno-chromatography test strip.

[0167] According to Claim 79 of the present invention, in the chromatography quantitative measuring apparatus as defined in Claim 78, the carrier is bent to create a space between the fixing table and the end of the carrier.

[0168] Therefore, the immuno-chromatography test strip can be detached easily.

[0169] According to Claim 80 of the present invention, in the chromatography quantitative measuring apparatus as defined in Claim 79, the carrier is provided with a groove to be bent therealong.

[0170] Therefore, the carrier is easily bent, so that the immuno-chromatography test strip can be detached simply.

[0171] According to Claim 81 of the present invention, in the chromatography quantitative measuring apparatus as defined in Claim 78, the carrier protrudes above the fixing table.

[0172] Therefore, the carrier is easy for an operator to hold when detaching the immuno-chromatography test strip, resulting in enhancement in operability.

[0173] According to Claim 82 of the present invention, in the chromatography quantitative measuring apparatus as defined in Claim 78, a part of the carrier is provided with a slip stopper.

[0174] Therefore, the carrier is easy for an operator to hold when detaching the immuno-chromatography test strip, resulting in enhancement in operability.

[0175] According to Claim 83 of the present invention, in the chromatography quantitative measuring apparatus as defined in Claim 40, the fixing table is provided with a groove for receiving the inspection target solution.

[0176] Therefore, a sample which erroneously escapes during the application of sample to the immuno-chromatography test strip is prevented from adhering to the measuring apparatus.

[0177] According to Claim 84 of the present invention, in the chromatography quantitative measuring apparatus as defined in Claim 83, the groove is given a slope, so that the inspection target solution can be supplied to the development layer from the direction of the cross section of the immuno-chromatography test strip.

[0178] Therefore, the fixing table is applicable to other types of test strips.

[0179] According to Claim 85 of the present invention,

in the chromatography quantitative measuring apparatus as defined in Claim 40, the fixing table is subjected to water repellent finishing.

[0180] Therefore, a sample which erroneously escapes during the application of sample to the immuno-chromatography test strip can be easily wiped.

[0181] According to Claim 86 of the present invention, in the chromatography quantitative measuring apparatus as defined in Claim 40, the fixing table is attached with an absorbent material.

[0182] Therefore, a sample which erroneously escapes during the application of sample to the immuno-chromatography test strip is absorbed by the absorbent material, so that the sample is prevented from adhering to the measuring apparatus.

[0183] According to Claim 87 of the present invention, in the chromatography quantitative measuring apparatus as defined in Claim 40, the fixing table has a through hole in which a removal bar can be inserted, and the bar is inserted in the through hole to press the immuno-chromatography test strip, thereby removing the immuno-chromatography test strip from the fixing table.

[0184] Therefore, an operator is not contaminated with a sample when detaching the immuno-chromatography test strip.

[0185] According to Claim 88 of the present invention, in the chromatography quantitative measuring apparatus as defined in Claim 87, the removal bar is integrated with the fixing table.

[0186] Therefore, it is possible to prevent a loss of the bar.

#### BRIEF DESCRIPTION OF DRAWINGS

[0187]

Figures 1 are diagrams illustrating the configuration of a chromatography quantitative measuring apparatus according to a first embodiment.

Figures 2 are cross sectional views of a chromatography quantitative measuring apparatus according to a second embodiment from the viewpoint of the direction in which a sample is developed, and from the viewpoint of the direction perpendicular to the direction in which the sample is developed.

Figures 3 are cross sectional views of another chromatography quantitative measuring apparatus according to the second embodiment from the viewpoint of the direction in which the sample is developed, and from the viewpoint of the direction perpendicular to the direction in which the sample is developed.

Figure 4 is a diagram illustrating the configuration of a chromatography quantitative measuring apparatus according to a third embodiment.

Figure 5 is a diagram illustrating the configuration of a chromatography quantitative measuring apparatus according to a fourth embodiment.

Figure 6 is a diagram illustrating the configuration of a chromatography quantitative measuring apparatus according to a fifth embodiment.

Figures 7 are diagrams schematically illustrating the configuration of a chromatography quantitative measuring apparatus according to a sixth embodiment.

Figures 8 are diagrams showing a change in absorbance which accompanies development of an inspection target solution, according to the sixth embodiment.

Figures 9 are diagrams showing a change in absorbance in a state where an optical beam is kept being applied according to a seventh embodiment. Figures 10 are diagrams showing results of measuring absorbances on a chromatography test strip when different inspection target solutions are employed, according to an eighth embodiment.

Figures 11 are diagrams illustrating development of an inspection target solution on a chromatography test strip according to a ninth embodiment.

Figures 12 are diagrams illustrating a measurement of a difference in absorbance on a chromatography test strip according to a tenth embodiment.

Figures 13 are diagrams illustrating an electrical noise of an absorbance signal on a chromatography test strip according to an eleventh embodiment.

Figures 14 are diagrams illustrating an optical noise of an absorbance signal on a chromatography test strip according to a twelfth embodiment.

Figure 15 is a diagram illustrating absorbance on a chromatography test strip including absorbance at a marker reagent hold part, according to a thirteenth embodiment.

Figure 16 is a diagram illustrating a method for detecting a peak value of absorbance on a chromatography test strip according to a fourteenth embodiment.

Figure 17 is a perspective view of a chromatography measuring apparatus according to a fifteenth embodiment.

Figure 18 is a perspective view of a chromatography quantitative measuring apparatus according to a sixteenth embodiment.

Figure 19 is a cross sectional view of a chromatography quantitative measuring apparatus which is provided with a projection on a measurement table and holes in a carrier and a fixing table, in which the projection can be inserted.

Figures 20 are perspective views of a chromatography quantitative measuring apparatus according to a seventeenth embodiment.

Figure 21 is a cross sectional view of a chromatography quantitative measuring apparatus according to an eighteenth embodiment.

Figure 22 is a perspective view of a chromatography quantitative measuring apparatus according to a nineteenth embodiment.

Figure 23 is a perspective view of a chromatography quantitative measuring apparatus according to a twentieth embodiment.

Figure 24 is a cross sectional view of a chromatography quantitative measuring apparatus which is provided with a through-hole in a fixing table, which a removal bar can penetrate.

Figures 25 are diagrams showing an example of a conventional chromatography quantitative measuring apparatus.

## BEST MODE TO EXECUTE THE INVENTION

[0188] Hereinafter, embodiments according to the present invention will be described with reference to the drawings. The embodiments described here are given only as examples and the present invention is not restricted to these embodiments.

### (Embodiment 1)

[0189] Hereinafter, a chromatography quantitative measuring apparatus that corresponds to the invention defined in Claims 1 to 6 of the present invention will be described as a first embodiment with reference to figures 1.

[0190] Figure 1(a) is a diagram schematically illustrating the configuration of a reflective spectrophotometer as the chromatography quantitative measuring apparatus according to the first embodiment. Figure 1(b) is a diagram illustrating the constitution of a chromatography test strip. In the drawings, the same or corresponding constituent elements as those shown in figures 25 are denoted by the same reference numerals, and descriptions thereof will be omitted.

[0191] In figure 1, numeral 101 denotes a semiconductor laser as a light source, numeral 102 denotes a collimator lens which converts a beam emitted from the semiconductor laser 101 into a collimated beam, numeral 103 denotes a polarization beam splitter which polarizes the beam that has passed through the aperture 4, numeral 104 denotes a photodiode A which monitors the reference beam 6, and numeral 105 denotes a cylindrical lens which leads the beam that has passed through the polarization beam splitter 103 to the immuno-chromatography test strip 8. Numeral 106 denotes a photodiode B which receives the scattering light 9 from the immuno-chromatography test strip 8.

[0192] An operation of the so-configured chromatography quantitative measuring apparatus will be described.

[0193] When an inspection target solution is applied to the application part 81 and the sample is developed, a beam is applied to the chromatography test strip 8 from the semiconductor laser 101 in order to measure the concentration of an analysis target included in the inspection target solution. The beam emitted from the semiconductor laser 101 is converted into a collimated

beam via the collimator lens 102. The wavelength of the semiconductor laser 101 is 635nm. The wavelength is so decided for the reason that by this wavelength, there can be obtained a sufficient difference between absorbance of a gold colloid as a marker reagent and absorbance of blood (erythrocyte) as a sample, as well as sufficient absorbance sensitivity of the gold colloid, and this wavelength is used for an optical disk or the like.

[0194] The collimated beam obtained by the collimator lens 102 is input to the polarization beam splitter 103 through the aperture 4 ( $\varnothing 3\text{mm}$ ). This polarization beam splitter 103 is used in order to take advantage of light effectively by utilizing the polarization characteristic of a laser. The beam reflected (separated) at the polarization beam splitter 103 is received by the photodiode A 104 as the reference beam 6. On the other hand, the beam transmitted through the polarization beam splitter 103 is input to the cylindrical lens 105. By the cylindrical lens 105, the beam is focused only in the direction orthogonal with respect to the width of the immuno-chromatography test strip 8 (the direction of a long side). As shown in figure 1(b), the immuno-chromatography test strip 8 described with respect to the first embodiment is approximately 50mm long by 5mm wide, and the detection part 83 thereof is approximately 1mm long. Accordingly, the beam applied in the first embodiment is an elliptical beam 100 which has a major axis of 3mm and a minor axis of 0.4mm, in consideration of an error in attachment of the immuno-chromatography test strip 8, the accuracy of scanning, and the like. When the elliptical beam 100 is constituted by the cylindrical lens 105, the efficiency in light utilization will be five times as high as that when the elliptical beam 100 is constituted by the aperture 4.

[0195] Then, the scattering light 9 from the immuno-chromatography test strip 8 is received by the photodiode B 106. The photodiode B 106 is arranged 30mm apart from the sample with an inclination by  $45^\circ$  with respect to the axis of the beam applied to the immuno-chromatography test strip 8. The area of the photodiode B 106 for receiving light is  $10 \times 10\text{mm}$ , where the scattering light 9 with power approximately  $1/1000$  as high as the emission power of the semiconductor laser 101 is received.

[0196] Outputs from the photodiodes 104 and 106, which have received the reference beam 6 and the scattering light 9 in this way, are respectively subjected to Log transformation, and a value obtained by doing subtraction with these Log transformed values is output as an absorbance signal.

[0197] By the above-described configuration, light is effectively utilized by using the laser, whereby a measurement is fairly possible with the photodiodes even without any use of photomultiplier tube is used, resulting in a reduction in the cost of the apparatus. There is previously obtained a calibration curve indicating a relationship between the difference between the absorbance signal of the base part 84 at the immuno-chromatogra-

phy test strip 8 and the absorbance signal at the detection part 83, and the concentration of a sample to be measured. By detecting the difference between the absorbance signal at the base part 84 and that at the detection part 83 where an actual sample is applied, the concentration of the sample is obtained through the calibration curve in consideration of a known difference between the absorbance signal at the base part 84 and that at the detection part 83. In the above-described configuration, the immuno-chromatography test strip 8 is scanned in the longitudinal direction, thereby measuring the difference between the absorbance signal at the base part 84 and that at the detection part 83 with a single beam. Further, also when the beam is scanned by moving the whole optical system, the difference between the absorbance signal at the base part 84 and that at the detection part 83 can be similarly obtained with a single beam.

[0198] Further, influence of non-uniform coloration in the direction of the width of the immuno-chromatography test strip 8 can be reduced by the elliptical beam. However, an attention should be paid when the major axis of the elliptical beam is 5mm or more, because the elliptical beam 100 might easily protrude the immuno-chromatography test strip 8 due to scanning thereof or the like, which results in an error factor. Further, an attention should be also paid with respect to the fact that sensitivity of the absorbance is low when the minor axis is 1mm or more, and influence of non-uniform coloration is increased when the beam is totally focused, which results in error factor.

[0199] While in figure 1 the beam is formed into an elliptical shape by employing the cylindrical lens 105, the beam may be formed into a rectangular shape by employing a rectangular aperture 4a as shown in figure 2, instead of the aperture 4 in figure 1, and eliminating the cylindrical lens.

[0200] As described above, according to the chromatography quantitative measuring apparatus of the first embodiment, the semiconductor laser 101 is employed as a light source, the beam emitted therefrom is formed into an elliptical shape by an optical means such as the cylindrical lens 105, or into a rectangular shape by means of the aperture 4a, and the elliptically or rectangularly shaped beam is applied to the immuno-chromatography test strip 8 where a sample is applied. Therefore, a part as the light source can be downsized and the cost thereof is reduced. Further, by employing the beam in elliptical shape or the like, influence of non-uniform coloration in the direction of the width of the immuno-chromatography test strip 8 can be reduced, thereby enhancing the accuracy of quantitative analysis.

[0201] Further, the difference between the absorbance signal at the base part 84 of the immuno-chromatography test strip 8 and the absorbance signal at the detection part 83 can be obtained by scanning the beam over the immuno-chromatography test strip 8, thereby performing an effective measurement.

(Embodiment 2)

**[0202]** Next, a chromatography quantitative measuring apparatus that corresponds to the invention defined in Claims 7 and 8 of the present invention will be described as a second embodiment with reference to figures 2 and 3.

**[0203]** Figures 2 are cross sectional views of an optical system, a reflective spectrophotometer, as the chromatography quantitative measuring apparatus according to the second embodiment, from the viewpoint of the direction in which a sample is developed (figure 2(a)), and from the viewpoint of the direction perpendicular to the direction in which the sample is developed (figure 2(b)).

**[0204]** In figures 2, a beam emitted from the semiconductor laser 101 is converted into a collimated beam via the collimator lens 102. The collimated beam is input to the polarization beam splitter 103 through the aperture 4a (3×0.4mm). Then, the beam reflected at the polarization beam splitter 103 is received by the photodiode A 104 as the reference beam 6. On the other hand, the beam transmitted through the polarization beam splitter 103 is applied to the immuno-chromatography test strip 8. As described above, the immuno-chromatography test strip 8 according to the second embodiment is also approximately 50mm long by 5mm wide, and the detection part 83 thereof is approximately 1mm long. Accordingly, the beam applied in the second embodiment is a rectangular beam 100 which has a longer side of 3mm and a shorter side of 0.4mm, in consideration of an error in attachment of the immuno-chromatography test strip 8, the accuracy of scanning, and the like. In the configuration in figures 2, at this time, when the direction 107 in which the beam divergence angle of the semiconductor laser 101 becomes larger is made to correspond to direction of a longer side of the rectangular beam, the direction 108 in which the beam divergence angle of the semiconductor laser 101 becomes smaller corresponds to the direction of a shorter side of the rectangular beam, resulting in disposition with the highest light utilization efficiency. Further, since distribution of optical power in the longer-side direction is smoothed, non-uniform coloration in the direction of the width of the immuno-chromatography test strip 8 is further reduced.

**[0205]** Further, figures 3 are cross sectional views of another optical system as a reflective spectrophotometer according to the second embodiment, from the viewpoint of the direction in which a sample is developed (figure 3(a)), and from the viewpoint of the direction perpendicular to the direction in which the sample is developed (figure 3(b)).

**[0206]** In figures 3, a beam emitted from the semiconductor laser 101 is converted into a collimated beam via the collimator lens 102. The collimated beam is input to the polarization beam splitter 103 through the aperture 4 (Ø3mm). Then, the beam reflected at the polarization beam splitter 103 is received by the photodiode A 104

as the reference beam 6. On the other hand, the beam transmitted through the polarization beam splitter 103 is input to the cylindrical lens 105. By the cylindrical lens 105, the beam is focused only in the direction orthogonal with respect to the width (the direction of a long side) of the immuno-chromatography test strip 8. As described above, the beam to be applied is the elliptical beam 100 which has a major axis of 3mm and a minor axis of 0.4mm, in consideration of an error in attachment of the immuno-chromatography test strip 8, the accuracy of scanning, and the like. In the configuration in figures 3, at this time, when the direction 107 in which the beam divergence angle of the semiconductor laser 101 becomes larger is made to correspond to the direction of the major axis of the elliptical beam, the direction 108 in which the beam divergence angle of the semiconductor laser 101 becomes smaller corresponds to the direction of the minor axis of the elliptical beam. Therefore, as compared with the configuration shown with respect to the first embodiment in figure 1, which does not adopt the above-described construction of making the direction 107 in which the beam divergence angle of the semiconductor laser 101 becomes larger correspond to the direction of the major axis of the elliptical beam, while there is no difference in the light utilization efficiency, distribution of optical power in the direction of the major axis is smoothed, and thus non-uniform coloration in the direction of the width of the immuno-chromatography test strip 8 is further reduced.

**[0207]** As described above, according to the chromatography quantitative measuring apparatus of the second embodiment, the direction 107 in which the beam divergence angle of the laser beam emitted from the semiconductor laser 101 becomes larger is made to correspond to the direction of a longer side of the beam which is shaped rectangularly by employing the aperture 4a, or to the direction of the major axis of the beam which is shaped elliptically by employing the cylindrical lens 105, and the beam is applied so that the direction of a long side (the direction of a longer side, or the direction of the major axis) of the beam is orthogonal with respect to the direction of a long side of the immuno-chromatography test strip 8. Thereby, distribution of optical power of the beam in the direction of the major axis is smoothed, and thus non-uniform coloration in the direction of the width of the immuno-chromatography test strip 8 is further reduced.

(Embodiment 3)

**[0208]** Hereinafter, a chromatography quantitative measuring apparatus that corresponds to the invention defined in Claims 9 and 10 of the present invention will be described as a third embodiment with reference to figure 4.

**[0209]** Figure 4 is a diagram schematically illustrating the configuration of a reflective spectrophotometer as the chromatography quantitative measuring apparatus

according to the third embodiment. In the drawing, the same or corresponding constituent elements as those shown in figures 1 are denoted by the same reference numerals, and descriptions thereof will be omitted.

[0210] In figure 4, numeral 109 denotes a temperature sensor provided in the vicinity of the semiconductor laser 101, and numeral 110 denotes a calculator which calculates the concentration of a sample from an absorbance signal that is compensated with reference to output from the temperature sensor 109. In the calculator 110 for performing compensation, Log transformation circuits for detecting optical signals and a circuit that constitutes a difference device for obtaining the converted concentration of the sample, or the like are integrally configured.

[0211] An operation of the so-configured chromatography quantitative measuring apparatus will be described.

[0212] When an inspection target solution is applied to the application part 81 and the sample is developed, a beam is applied to the chromatography test strip 8 from the semiconductor laser 101 in order to measure the concentration of an analysis target included in the inspection target solution. The beam emitted from the semiconductor laser 101 is converted into a collimated beam via the collimator lens 102. The wavelength of the semiconductor laser 101 is 635nm. The collimated beam is input to the polarization beam splitter 103 through the aperture 4 ( $\varnothing 3\text{mm}$ ). The beam reflected at the polarization beam splitter 103 is received by the photodiode A 104 as the reference beam 6. On the other hand, the beam transmitted through the polarization beam splitter 103 is input to the cylindrical lens 105, and focused only in the direction orthogonal with respect to the width (the direction of a long side) of the immuno-chromatography test strip 8 by the cylindrical lens 105. Then, the scattering light 9 from the immuno-chromatography test strip 8 is received by the photodiode B 106. Outputs from the photodiodes 104 and 106, which have received the reference beam 6 and the scattering light 9, are respectively subjected to A/D conversion and input to the calculator 110.

[0213] Here, for example, in a case where a marker reagent is a gold colloid and a sample is blood (erythrocyte), when the wavelength of the beam from the semiconductor laser 101 is changed from 635nm to 655nm, the absorbance is reduced by approximately 30%. Further, according to temperature change, the wavelength is changed by approximately  $0.2\text{nm}/^{\circ}\text{C}$  in case of, for example, a commercially available semiconductor laser HL6333MG which is manufactured by Hitachi, Ltd. Thus, a large margin of error is generated unless compensation.

[0214] As described above, since an error in the absorbance is generated due to variation of wavelength of the beam, the initial wavelength of the semiconductor laser 101 is input to the calculator, and the amount of temperature change is detected by the temperature

sensor 109 provided in the vicinity of the semiconductor laser 101 and input to the calculator. Then, in the calculator 110, outputs from the photodiodes 104 and 106 are subjected to Log transformation, and subtraction is done with these Log transformed values, thereby obtaining an absorbance signal. At this time, the present wavelength is calculated from the initial wavelength of the semiconductor laser 101 and the amount of temperature change, and the absorbance signal is compensated from this present wavelength. Finally, the concentration of a sample is obtained from this compensated absorbance signal.

[0215] As described above, the chromatography quantitative measuring apparatus according to the third embodiment includes the temperature sensor 109 provided in the vicinity of the semiconductor laser 101, and the calculator 110 which calculates the concentration of a sample by compensating a value of difference between outputs from the photodiodes 104 and 106 on the basis of the output from the temperature sensor 109. Therefore, influence due to hardware configuration and usage environment is reduced, resulting in a quantitative measurement with fewer measurement errors.

[0216] Further, the Log transformation circuits for detecting optical signals, and the circuits which constitute the difference device for obtaining the converted concentration of the sample, or the like are integrally configured, thereby reducing the size of the apparatus.

[0217] While in the third embodiment the description has been given of the case where the temperature sensor 109 and the calculator 110 are provided in the chromatography quantitative measuring apparatus shown in figure 1, the chromatography quantitative measuring apparatus shown in figures 2 may be also provided with the temperature sensor 109 and the calculator 110, so that the present wavelength is calculated from the initial wavelength of the semiconductor laser 101 and the amount of temperature change, and an absorbance signal is compensated from this present wavelength.

(Embodiment 4)

[0218] Next, a chromatography quantitative measuring apparatus that corresponds to the invention defined in Claims 11 to 13 of the present invention will be described as a fourth embodiment with reference to figure 5.

[0219] Figure 5 is a diagram schematically illustrating the configuration of a reflective spectrophotometer as the chromatography quantitative measuring apparatus according to the fourth embodiment. In the drawing, the same or corresponding constituent elements as those shown in figures 25 are denoted by the same reference numerals, and descriptions thereof will be omitted.

[0220] In figure 5, numeral 111 denotes a concave mirror which condenses the scattering light 9 from the immuno-chromatography test strip 8.

[0221] An operation of the so-configured chromatog-



raphy quantitative measuring apparatus will be described.

[0222] When an inspection target solution is applied to the application part 81 and the sample is developed, a beam is applied to the chromatography test strip 8 from the semiconductor laser 101 in order to measure the concentration of an analysis target included in the inspection target solution. The beam emitted from the semiconductor laser 101 is converted into a collimated beam via the collimator lens 102. The collimated beam is input to the polarization beam splitter 103 through the aperture 4 ( $\varnothing 3\text{mm}$ ). The beam reflected at the polarization beam splitter 103 is received by the photodiode A 104 as the reference beam 6. On the other hand, the beam transmitted through the polarization beam splitter 103 is input to the cylindrical lens 105, and focused only in the direction orthogonal with respect to the width (the direction of a long side) of the immuno-chromatography test strip 8 by the cylindrical lens 105. Then, the scattering light 9 from the immuno-chromatography test strip 8 is received by the photodiode B 106. At this time, the concave mirror 111 condenses a scattering light from the immuno-chromatography test strip 8 which goes in the opposite direction of a scattering light that goes toward the photodiode B 106, with the laser beam input from the semiconductor laser 101 to the immuno-chromatography test strip 8 as an axis of symmetry, on the photodiode B 106.

[0223] The photodiode B 106 is arranged 30mm apart from the sample with an inclination by  $45^\circ$  with respect to the axis of the beam applied to the immuno-chromatography test strip 8. The area of the photodiode B 106 for receiving light is  $10 \times 10\text{mm}$ , where the scattering light 9 with power approximately  $1/1000$  as high as the emission power of the semiconductor laser 101 is received. Outputs from the photodiodes A 104 and B 106, which have received the reference beam 6 and the scattering light 9, are respectively subjected to Log transformation, and the result of subtraction with these Log transformed values is output as an absorbance signal, as described in figure 1. There is previously obtained a calibration curve indicating a relationship between the difference between the absorbance signal at the base part 84 of the immuno-chromatography test strip 8 and the absorbance signal at the detection part 83, and the concentration of sample to be measured. By detecting the difference between the absorbance signal at the base part 84 and that at the detection part 83 where an actual sample is applied, the concentration of the sample is obtained through the calibration curve in consideration of a known difference between the absorbance signal at the base part 84 and that at the detection part 83. At this time, the reference beam 6 has a beam diameter of  $\varnothing 3\text{mm}$ , and thus the area of the photodiode A 104 for receiving light may be approximately  $5 \times 5\text{mm}$ , resulting in a photodiode that is lower in price than the photodiode B 106. Further, by using the concave mirror 111, the scattering light 9 can be condensed more effec-

tively, resulting in a measurement of the absorbance with a higher S/N ratio.

[0224] As described above, the chromatography quantitative measuring apparatus according to the fourth embodiment is provided with the concave mirror 111, so that, among the scattering light 9 from the immuno-chromatography test strip 8, a scattering light which goes in the symmetrical direction with respect to the direction of the photodiode B 106, with the optical axis of the semiconductor laser as an axis of symmetry, is effectively condensed on the photodiode B 106. Therefore, a measurement of the absorbance with a higher S/N ratio can be performed.

[0225] While in the fourth embodiment the description has been given taking the case where the area of the photodiode A 104 for receiving light is reduced and the concave mirror 111 is provided in the chromatography quantitative measuring apparatus shown in figure 1, as an example, the chromatography quantitative measuring apparatus shown in figure 2 is similarly applicable.

#### (Embodiment 5)

[0226] Next, a chromatography quantitative measuring apparatus that corresponds to the invention defined in Claim 14 of the present invention will be described as a fifth embodiment with reference to figure 6.

[0227] Figure 6 is a diagram schematically illustrating the configuration of a reflective spectrophotometer as the chromatography quantitative measuring apparatus according to the fifth embodiment. In the drawing, the same or corresponding constituent elements as those shown in figures 25 are denoted by the same reference numerals, and descriptions thereof will be omitted.

[0228] In figure 6, numeral 112 denotes a condensing lens for effectively condensing the scattering light 9 from the immuno-chromatography test strip 8 on a photodiode B 106a that is smaller than the above-described photodiode B 106.

[0229] An operation of the so-configured chromatography quantitative measuring apparatus will be described.

[0230] When an inspection target solution is applied to the application part 81 and the sample is developed, a beam is applied to the chromatography test strip 8 from the semiconductor laser 101 in order to measure the concentration of an analysis target included in the inspection target solution. The beam emitted from the semiconductor laser 101 is converted into a collimated beam via the collimator lens 102. The collimated beam is input to the polarization beam splitter 103 through the aperture 4 ( $\varnothing 3\text{mm}$ ). The beam reflected at the polarization beam splitter 103 is received by the photodiode A 104 as the reference beam 6. On the other hand, the beam transmitted through the polarization beam splitter 103 is input to the cylindrical lens 105, and focused only in the direction orthogonal with respect to the direction of a long side of the immuno-chromatography test strip

8 by the cylindrical lens 105. Then, the scattering light 9 from the immuno-chromatography test strip 8 is received by the photodiode B 106a. At this time, the condensing lens 112 is arranged in front of the photodiode B 106a, and the scattering light 9 is effectively condensed by this condensing lens 112.

[0231] Outputs from the photodiodes A 104 and B 106a, which have received the reference beam 6 and the scattering light 9, are respectively subjected to Log transformation, and the result of subtraction with these Log transformed values is output as an absorbance signal, as described in figure 1. There is previously obtained a calibration curve indicating a relationship between the difference between the absorbance signal at the base part 84 of the immuno-chromatography test strip 8 and the absorbance signal at the detection part 83, and the concentration of a sample to be measured. By detecting the difference between the absorbance signal, at the base part 84 and that at the detection part 83 where an actual sample is applied, the concentration of the sample is obtained through the calibration curve in consideration of a known difference between the absorbance at the base part 84 and that at the detection part 83.

[0232] As described above, the chromatography quantitative measuring apparatus according to the fifth embodiment is provided with the condensing lens 112 which effectively condenses a scattering light that goes toward the photodiode B 106a, among the scattering light 9 from the immuno-chromatography test strip 8, on the photodiode B 106a. Therefore, the area of the photodiode B 106a for receiving light, that is, the size of the photodiode B 106a can be reduced without decrease in the amount of light received by the photodiode B 106a, whereby a low cost photodiode can be adopted, resulting in a reduction in the cost and size of the apparatus.

[0233] Further, by reducing the areas of the photodiode A 104 and photodiode B 106a for receiving lights, a speed of response of the photodiodes can be improved, and thus a speed of scanning of the immuno-chromatography test strip 8 is improved, thereby shortening a measurement time.

[0234] While in the fifth embodiment the description has been given taking the case where the condensing lens 112 is provided and the area of the photodiode B 106 is reduced in the chromatography quantitative measuring apparatus shown in figure 1, as an example, the chromatography quantitative measuring apparatuses shown in figures 2 and 3 may be also provided with the condensing lens 112 between the photodiode B 106 for receiving a scattering light and the immuno-chromatography test strip 8, so that the scattering light 9 is received effectively.

#### (Embodiment 6)

[0235] Hereinafter, a chromatography quantitative measuring apparatus that corresponds to the invention

defined in Claims 15 to 19 of the present invention will be described as a sixth embodiment with reference to figures 7 and 8.

[0236] Figures 7 are diagrams schematically illustrating the configuration of the chromatography quantitative measuring apparatus according to the sixth embodiment of the present invention. Figure 7(a) is a diagram schematically illustrating the configuration of the measuring apparatus, and figure 7(b) is a diagram illustrating the constitution of a chromatography test strip.

[0237] In figure 7(a), a beam emitted from a semiconductor laser 201 is converted into a collimated beam by passing through a collimator lens 202. The collimated beam is input to a beam splitter 203 through the aperture 4. Here, a part of the optical beam reflected at the beam splitter 203 is received by a first photodiode 204 as the reference beam 6. On the other hand, the rest of the optical beam that is transmitted through the beam splitter 203 is condensed by a cylindrical lens 205 only in the direction of a longer side of the immuno-chromatography test strip 8, and applied to the chromatography test strip 8 as an elliptical beam 211. Further, the scattering light 9 is generated from the surface of the chromatography test strip 8 and received by a second photodiode 206.

[0238] Next, outputs from the first photodiode 204 which has received the reference beam 6 and the second photodiode 206 which has received the scattering light 9 are respectively subjected to Log transformation, and a value obtained by subtracting a Log transformed value for the second photodiode 206 from a Log transformed value for the first photodiode 204 is output as an absorbance signal.

[0239] As shown in figure 7(b), the chromatography test strip 8 comprises the application part 81 where an inspection target solution is applied, the marker reagent hold part 82 which holds a marker reagent which can be eluted by development of the inspection target solution, a base part 84 where a specific binding reaction is caused between the marker reagent and an analysis target included in the inspection target solution, and a detection part 83 where a bounded material of the marker reagent and the analysis target is immobilized.

[0240] An operation of the so-configured chromatography quantitative measuring apparatus will be described with reference to figures 7.

[0241] First, when an inspection target solution is applied to the application part 81, the inspection target solution is developed. At this time, when the inspection target solution reaches the marker reagent hold part 82, a marker reagent is eluted and specifically bonded to an analysis target included in the inspection target solution. Then, this bounded material is immobilized at the detection part 83, and a non-immobilized residual marker reagent flows downstream in the direction of the development, without being immobilized.

[0242] By detecting the difference between the absorbance signal at the detection part 83 of the chroma-

tography test strip 8 and the absorbance signal at the base part 84, the concentration of the analysis target included in the inspection target solution can be converted through a known calibration curve.

[0243] Here, by scanning the chromatography test strip 8 in the longer-side direction, the difference between the absorbance signal at the base part 84 and that at the detection part 83 can be measured with a single beam. Further, since the optical beam is elliptical, influence of non-uniform coloration according to positions in the direction of a shorter side of the chromatography test strip 8 is reduced.

[0244] Next, a description will be given of a measurement of the absorbance.

[0245] Figures 8 are diagrams illustrating the measurement of the absorbance on the chromatography test strip according to the sixth embodiment of the present invention. Figure 8(a) illustrates a state where the inspection target solution is developed on the chromatography test strip 8 and a position where the optical beam is applied. Figure 8(b) illustrates a change in absorbance signal with respect to a measurement time.

[0246] The chromatography test strip 8 is attached to the measuring apparatus, and an inspection target solution 212 is applied to the application part 81. With development of the inspection target solution 212, an analysis target included in the inspection target solution 212 is carried away, while being bounded to an eluted marker reagent, and a bounded material is immobilized at the detection part 83. When the absorbance is measured in a state where the optical beam 211 is continuously applied to the detection part 83, an absorbance signal 221 fluctuates sharply due to passing of the marker reagent, then rises gradually, and falls gradually again as the inspection target solution is dried.

[0247] In order to reduce an error in the measurement of the absorbance, the optical beam 211 is kept being applied between the marker reagent hold part 82 and the downstream end of the base part 84, a change in absorbance due to the elution of the marker reagent is detected, and a measurement is automatically started after passage of prescribed period of time since the detection of the change in absorbance.

[0248] The above-mentioned prescribed period of time could affect a speed of development of the inspection target solution according to temperature and humidity around the measuring apparatus. Then, temperature and humidity are monitored from when the marker reagent is eluted with the development of the inspection target solution until when the concentration of the analysis target is measured, thereby compensating the prescribed period of time. Further, the optical beam is repeatedly lighted and extinguished alternately while the development of the inspection target solution is detected. Or, a time to detect the development of the inspection target solution is predicted, and the optical beam is extinguished until shortly before the predicted arrival time. Or, output of the optical beam is set lower than that

at measurement while the development of the inspection target solution is detected.

[0249] As described above, according to the chromatography quantitative measuring apparatus of the sixth embodiment, the inspection target solution is applied to the chromatography test strip 8, and the concentration of the analysis target included in the inspection target solution is measured after a prescribed period of time since the elution of the marker reagent, which accompanies the development of the inspection target solution, is detected. Therefore, an inspector does not need to manage time manually, and a used test strip where a marker reagent is already eluted can be discriminated because the measurement is performed after the elution of the marker reagent is detected.

[0250] Further, surrounding temperature and humidity are monitored, so that time from when the elution of the marker reagent is detected until when the measurement is performed is compensated, thereby reducing influence of surrounding temperature and humidity on a variation in speed of development of the inspection target solution on the chromatography test strip.

[0251] Furthermore, the optical beam is repeatedly lighted and extinguished alternately while the development of the inspection target solution is detected. Or, a time to detect the development of the inspection target solution is predicted, and the optical beam is extinguished until shortly before the predicted arrival time. Or, laser output is set lower than that at measurement while the development of the inspection target solution on the chromatography test strip is detected. Or, the above-described methods are combined. Therefore, it is possible to prevent deterioration in performance of the chromatography test strip, which accompanies temperature rise at a part for applying a laser to the chromatography test strip.

[0252] While in the sixth embodiment the description has been given of the detection of the elution of the marker reagent, the same effect will be also achieved when the development of the inspection target solution itself is detected.

#### (Embodiment 7)

[0253] Next, a chromatography quantitative measuring apparatus that corresponds to the invention defined in Claims 20 to 23 of the present invention will be described as a seventh embodiment with reference to figures 9.

[0254] Figures 9 are diagrams illustrating a measurement of absorbance on a chromatography test strip according to the seventh embodiment of the present invention. Figure 9(a) illustrates a state where the inspection target solution is developed on the chromatography test strip 8 and a position where an optical beam is applied. Figure 9(b) is an enlarged view illustrating a sharp rise in a change in absorbance in a state where the optical beam is kept being applied according to the seventh

embodiment of the present invention.

[0255] The optical beam 211 is kept being applied between the marker reagent hold part 82 and the detection part 83. The absorbance signal at this time increases monotonously with elution of the marker reagent.

[0256]—By obtaining inclination  $\theta$  of absorbance signal with respect to time variation, a speed of development of the inspection target solution 212 is calculated, and it is judged from the speed of development whether performance of the chromatography test strip is high or low. Or, the optical beam is scanned so that a value of rise in absorbance, which is due to the elution of the marker reagent, is kept constant, the speed of development of the inspection target solution 212 is calculated from a speed of scanning, and it is judged from the speed of development whether the performance of the chromatography test strip 8 is high or low.

[0257] Further, a discrimination value of the speed of development is compensated from a result of measuring at least one of surrounding temperature and humidity at the development of the inspection target solution on the chromatography test strip 8.

[0258] As described above, according to the chromatography quantitative measuring apparatus of the seventh embodiment, a speed of development of the inspection target solution after it is applied is detected, and it is judged from the speed of development whether performance of the chromatography test strip 8 is high or low. Therefore, it is possible to judge whether there is a defect such as abnormal clogging on the chromatography test strip 8.

[0259] Further, since the speed of development of the inspection target solution is calculated after the detection of time variation of value of a detection signal, which is generated by the elution of the marker reagent that accompanies the development of the inspection target solution, it is possible to judge whether there is a defect such as abnormal clogging on the chromatography test strip 8.

[0260] Furthermore, since the optical beam is scanned so that a value of the detection signal, which is generated by the elution of the marker reagent that accompanies the development of the inspection target solution, is kept constant, and the speed of development of the inspection target solution is calculated from a speed of scanning with the optical beam, it is possible to judge whether there is a defect such as abnormal clogging on the chromatography test strip 8.

[0261] Moreover, since a discrimination value of the speed of development is compensated from the result of measuring at least one of surrounding temperature and humidity at the development of the inspection target solution, it is possible to prevent an erroneous judgement as to whether performance of the chromatography test strip is high or low, which is due to influence of temperature or humidity.

(Embodiment 8)

[0262] Hereinafter, a chromatography quantitative measuring apparatus that corresponds to the invention defined in Claims 24 to 26 of the present invention will be described as an eighth embodiment with reference to figures 10.

[0263] Figures 10 are diagrams showing results of measuring absorbances on the chromatography test strip 8 according to the eighth embodiment of the present invention, when different inspection target solutions are employed. Figure 10(a) illustrates a state of scanning of an optical beam on the chromatography test strip 8. Figure 10(b) shows changes of absorbance signals with respect to the position of the optical beam.

[0264] On the chromatography test strip 8, the optical beam 211 is scanned down to a downstream base part 84b, after passing through the detection part 83 from an upstream base part 84a. The absorbance signals at this time differ according to kinds of inspection target solutions. For example, with respect to a whole blood sample and a blood plasma sample, the whole blood sample totally has a higher absorbance. Further, the absorbance at the base part 84 is constant regardless of the concentration of an analysis target included in the inspection target solution.

[0265] A signal detection position for discriminating a kind of inspection target solution is downstream of the detection part 83, and the absorbance at the base part 84 is detected and compared with a known absorbance that corresponds to the kind of each inspection target solution. Further, the kind of inspection target solution is discriminated from the absorbance at the base part 84, and a calibration curve corresponding to that kind is selected, thereby converting the concentration of the analysis target included in the inspection target solution.

[0266] As described above, according to the chromatography quantitative measuring apparatus of the eighth embodiment, a kind of inspection target solution is discriminated from the detection signal at the base part 84 on the chromatography test strip 8 where the inspection target solution is applied. Therefore, the kind of inspection target solution that is applied to the chromatography test strip 8 can be discriminated.

[0267] Further, since the base part 84 where the detection signal is measured is downstream of the detection part 83 in the direction of development, it is possible to prevent an discrimination of a kind of inspection target solution, which is due to influences of a marker reagent that is liable to remain at the base part 84a upstream of the detection part 83 as compared with the base part 84b downstream thereof.

[0268] Furthermore, since the kind of inspection target solution is discriminated from the detection signal at the base part 84, and a calibration curve corresponding to the inspection target solution can be selected previously, when plural kinds of inspection target solutions are measured, a user does not need to manually input

a kind of inspection target solution to the apparatus, resulting in an automatic measurement.

(Embodiment 9)

[0269] Hereinafter, a chromatography quantitative measuring apparatus that corresponds to the invention defined in Claims 27 and 28 of the present invention will be described as a ninth embodiment with reference to figures 11.

[0270] Figures 11 are diagrams illustrating streams of an inspection target solution on a chromatography test strip according to the ninth embodiment of the present invention. Figure 11(a) shows a case where the inspection target solution 212 is sufficiently applied to the application part 81. The applied inspection target solution 212 is developed on the chromatography test strip 8 over the marker reagent hold part 82, the upstream base part 84a, the detection part 83, and the downstream base part 84b, respectively, and reaches an end part that is further downstream of the downstream base part 84b.

[0271] Figure 11(b) shows a case where the inspection target solution 212 applied to the application part 81 is insufficient. The applied inspection target solution 212 does not reach the end part downstream of the downstream base part 84b.

[0272] Then, an optical beam is applied to the end part downstream of the downstream base part 84b, and a value of a detection signal obtained in that case is judged. Further, in order to measure the concentration of an analysis target, the same optical beam as the optical beam 211 that is scanned in the vicinity of the detection part 83 is further scanned down to the end part downstream of the downstream base part 84b.

[0273] As described above, according to the chromatography quantitative measuring apparatus of the ninth embodiment, deficiency in the amount of inspection target solution applied, and insufficient development on the chromatography test strip 8 are judged from the detection signal obtained by applying the optical beam to the end part downstream of the downstream base part 84b on the chromatography test strip 8 where the inspection target solution is applied. Therefore, it is possible to detect deficiency in the amount of the inspection target solution 212 applied to the chromatography test strip 8, and insufficient development on the chromatography test strip 8 which is generated by clogging or the like.

[0274] Further, since the optical beam as is scanned down to the end part that is downstream of the base part 84 on the chromatography test strip 8, no new light source is required to detect deficiency in the amount of inspection target solution applied and insufficient development on the chromatography test strip 8, thereby restraining increase in the size and cost of the apparatus that accompany addition of the function.

(Embodiment 10)

[0275] Hereinafter, a chromatography quantitative measuring apparatus that corresponds to the invention defined in Claim 29 of the present invention will be described as a tenth embodiment with reference to figures 12.

[0276] Figures 12 are diagrams illustrating a measurement of absorbance on a chromatography test strip according to the tenth embodiment of the present invention. Figure 12(a) illustrates a state of scanning of an optical on the chromatography test strip 8, and figure 12 (b) shows a variation of absorbance signal with respect to the position of the optical beam.

[0277] On the chromatography test strip 8, the optical beam 211 is scanned down to the downstream base part 84b, after passing through the detection part 83 from the upstream base part 84a.

[0278] With a value of absorbance at a position where influence of absorbance of a marker reagent immobilized at the detection part 83 is not exerted, that is, a position U, which is downstream of a position T where the absorbance signal 221 has a peak value, by a distance D, as a standard, the absorbance corresponding to the concentration of an analysis target is obtained as a value E, which is a between the value of absorbance at the position U and that at the peak position T at that time. In other words, though the value of absorbance at the peak position T includes absorption components of the inspection target solution itself, and this produces an error in a measurement of the absorbance of the marker reagent immobilized at the detection part 83, an influence of this error can be removed by taking the value of absorbance at the position U, (which corresponds to the absorption components of the inspection target solution itself) as a standard. Further, since the standard position is the position U that is not upstream but downstream of the detection part 83, it is possible to remove an error (F in figure 12(b)) in a measurement of the absorbance, which is due to a marker reagent liable to remain at the upstream base part 84a.

[0279] As described above, according to the chromatography test strip of the tenth embodiment, when a detection signal at a position which is downstream of the detection part 83 on the chromatography test strip 8 in the direction in which the inspection target solution is developed, where influence of the detection part 83 is not exerted, is a standard value, the detection signal at the detection part 83 is a signal for detecting the concentration to be measured. Therefore, it is possible to reduce an influence of an error in a measurement of the absorbance, which is due to a marker reagent liable to remain at the base part 84a upstream of the detection part 83 as compared with the base part 84b downstream thereof.

(Embodiment 11)

[0280] Hereinafter, a chromatography quantitative measuring apparatus that corresponds to the invention defined in Claims 30 and 31 of the present invention will be described as an eleventh embodiment with reference to figures 13.

[0281] Figures 13 are diagrams illustrating a measurement of absorbance on a chromatography test strip according to the eleventh embodiment of the present invention. Figure 13(a) illustrates a state of scanning of an optical beam on the chromatography test strip 8, and figure 13(b) illustrates a state where a sharp electrical noise 222 is added to a variation of absorbance signal with respect to the position of the optical beam.

[0282] On the chromatography test strip 8, the optical beam 211 is scanned down to the downstream base part 84b, after passing through the detection part 83 from the upstream base part 84a. At this time, data of the absorbance signal 221 is stored at intervals G in which a smooth variation is sufficiently detected.

[0283] The electrical noise 222 added to the absorbance signal 221 is generated from a power (such as a switching power) applied to an electric circuit, or a circuit for performing digital processing, and indicates a considerably sharp variation as compared with a scanning speed of the optical beam 211.

[0284] When values at the peak position T of the absorbance signal 221 and at the position U which is downstream of the position T by the distance D are to be obtained, average values of several data in the vicinity of the respective positions are applied thereto. Further, when the values at the peak position T of the absorbance signal 221 and at the position U which is downstream of the position T by the distance D are to be obtained, intermediate values (values of data that are located in the middle of respective data arranged in the order of size) of several data in the vicinity of the respective positions are applied thereto.

[0285] Further, the number of data for obtaining the above-described average values and intermediate values are defined within a range so that the reading of the smooth variation of the absorbance signal 221 is not disturbed.

[0286] As described above, according to the chromatography quantitative measuring apparatus of the eleventh embodiment, the detection signal at the detection part 83 has an average value of values about an extreme value, and a detection signal as a standard value has an average value of values in the vicinity of a position downstream of the detection part 83 in the direction in which the inspection target solution is developed, where influence of the detection part 83 is not exerted. Therefore, even when the electrical noise 222 is accidentally added to the detection signal, an influence on the result of calculation for obtaining the concentration of an analysis target can be reduced.

[0287] Further, the detection signal at the detection

part 83 has an intermediate value of values about an extreme value, and the detection signal as a standard has an intermediate value of values in the vicinity of a position downstream of the detection part 83 in the direction in which the inspection target solution is developed, where influence of the detection part 83 is not exerted. Therefore, even when the electrical noise 222 is accidentally added to the detection signal, an influence on the result of calculation for obtaining the concentration of an analysis target can be further reduced as compared with the case where the average value is employed.

(Embodiment 12)

[0288] Hereinafter, a chromatography quantitative measuring apparatus that corresponds to the invention defined in Claims 32 and 33 of the present invention will be described as a twelfth embodiment with reference to figures 14.

[0289] Figures 14 are diagrams illustrating a measurement of absorbance on the chromatography test strip 8 according to the twelfth embodiment of the present invention. Figure 14(a) illustrates a state of scanning of an optical beam on the chromatography test strip 8, and figure 14(b) illustrates a state where optical noises 223 and 224 are added to a variation of absorbance signal with respect to the position of the optical beam. Figure 14(c) shows a normal variation of absorbance signal with respect to the position of the optical beam.

[0290] On the chromatography test strip 8, the optical beam 211 is scanned down to the downstream base part 84b, after passing through the detection part 83 from the upstream base part 84a. At this time, data of the absorbance signal 221 is stored at intervals G in which a smooth variation is sufficiently detected. Further, there are obtained an amount K of variation of the absorbance signal 221, which is previously measured on the normal chromatography test strip 8, in the vicinity of the peak position T (interval I), and an amount L of variation of the absorbance signal 221 in the vicinity of the downstream position U (interval J), and values of  $K+\alpha$  and  $L+\alpha$  ( $\alpha$  is tolerance for noise components) are stored as discrimination values at the respective positions.

[0291] The optical noises 223 and 224 added to the absorbance signal are generated by non-uniform immobilization of a marker reagent (alias, non-uniform coloration) at the detection part 83, non-uniform development of the marker reagent due to clogging at the downstream base part 84, a flaw on the surface of the chromatography test strip 8, or the like. The optical noises 223 and 224 disturb a smooth variation of the absorbance signal 221, and makes a normal measurement of the absorbance impossible according to the noise level.

[0292] Then, a comparison is made of values in the vicinity of the peak position T (interval I) of the absorbance signal 221, and when the difference between the maximum value and the minimum value exceeds the

discrimination value, the chromatography test strip 8 is judged to be low in performance. Further, a comparison is made of values in the vicinity of the position U, which is downstream of the peak position T of the absorbance signal 221 by the distance D, (interval J), and when the difference between the maximum value and the minimum value exceeds the discrimination value, the chromatography test strip 8 is judged to be low in performance.

[0293] As described above, according to the chromatography quantitative measuring apparatus of the twelfth embodiment, a comparison is made of the values about the extreme value of the detection signal, and when the difference therebetween exceeds the discrimination value, the chromatography test strip 8 is judged to be low in performance. Therefore, it is possible to avoid an erroneous measurement due non-uniform immobilization of the marker reagent at the detection part 83, a flaw on the surface of the chromatography test strip 8, or the like.

[0294] Further, a comparison is made of the values in the vicinity of the position downstream of the detection part 83 on the chromatography test strip 8 in the direction of development, where influence of the detection part 83 is not exerted, and when the difference therebetween exceeds the discrimination value, the chromatography test strip 8 is judged to be low in performance. Therefore, it is possible to avoid an erroneous measurement due to non-uniform development of the inspection target solution by clogging at the base part 84, a flaw on the surface of the chromatography test strip 8, or the like.

#### (Embodiment 13)

[0295] Hereinafter, a chromatography quantitative measuring apparatus that corresponds to the invention defined in Claims 34 to 37 of the present invention will be described as a thirteenth embodiment with reference to figure 15.

[0296] Figure 15 illustrates a state of scanning of an optical beam on the chromatography test strip 8 according to the thirteenth embodiment of the present invention, as well as a variation of absorbance signal with respect to the position of the optical beam.

[0297] A marker reagent remains at the marker reagent hold part 82 even after it is passed by an inspection target solution. Accordingly, in a measurement of a low-level analysis target, when the optical beam 211 is scanned from a position upstream of the marker reagent hold part 82, there are cases where the absorbance of the marker reagent remaining at the marker reagent hold part 82 has a place in the peak position. Further, since the residual marker reagent at the marker reagent hold part 82 is uniformly distributed, an absorbance signal 225 in this region is a flat signal.

[0298] Then, in order to avoid an erroneous recognition of the peak position, the optical beam 211 is

scanned from the position of the upstream base part 84a excluding the marker reagent hold part 82, and a measurement is started. Or, the flat absorbance signal 225 is detected, and discriminated from the absorbance at the peak position T which corresponds to the detection part 83.

[0299] Further, width H of the marker reagent hold part 83 is obtained from the width of the flat absorbance signal 225, and the obtained width H is compared with a prescribed width. Further, a value of the flat absorbance signal 225 is detected, and the amount of residual marker reagent is obtained.

[0300] As described above, according to the chromatography quantitative measuring apparatus of the thirteenth embodiment, at measurement of the concentration, since a measurement is performed on the chromatography test strip 8 exclusive of the marker reagent hold part 82, a measurement value of absorbance at the marker reagent hold part 82 is not included, whereby no erroneous recognition of the absorbance peak position occurs, resulting in a normal detection of the concentration of an analysis target.

[0301] Further, the region on the chromatography test strip 8 where the value of the detection signal is flat is taken as the region of the marker reagent hold part 82, whereby no erroneous recognition of the absorbance peak position occurs, resulting in a normal detection of the concentration of an analysis target.

[0302] Further, the width of the region on the chromatography test strip 8 where the value of the detection signal is flat is calculated, and the calculated width is compared with a prescribed width of the marker reagent hold part 82, so that the amount of marker reagent held can be confirmed, whereby it is possible to judge whether the chromatography test strip 8 is low in performance.

[0303] Further, the value in the region on the chromatography test strip 8 where the detection signal is flat is detected, and the amount of residual marker reagent is confirmed from the value, whereby it is possible to confirm whether the marker reagent has flown normally or not.

#### (Embodiment 14)

[0304] Hereinafter, a chromatography quantitative measuring apparatus that corresponds to the invention defined in Claims 38 and 39 of the present invention will be described as a fourteenth embodiment with reference to figure 16.

[0305] Figure 16 illustrates a state of scanning of an optical beam on the chromatography test strip 8 according to the fourteenth embodiment of the present invention, as well as a variation of absorbance signal 221 with respect to the position of the optical beam.

[0306] A marker reagent remains at the marker reagent hold part 82 even after it is passed by an inspection target solution. Accordingly, in a measurement of a low-level analysis target, when the optical beam 211 is



scanned from the position of the marker reagent hold part 82, there are cases where the absorbance of the marker reagent remaining at the marker reagent hold part 82 has a place in the peak position.

[0307] Then, a rise part 226 and a fall part 227 are detected from a variation in inclination of the absorbance signal 211, and the maximum position in an area between the rise part 226 and the fall part 227 is recognized as the peak position T.

[0308] Further, an interval between the rise part 226 and the fall part 227 is obtained, and the obtained interval is compared with a prescribed width of the detection part 83.

[0309] As described above, according to the chromatography quantitative measuring apparatus of the fourteenth embodiment, the rise part 226 and the fall part 227 of the detection signal are recognized, and the extreme value of the detection signal is obtained, whereby no erroneous recognition of the absorbance peak position occurs, resulting in a normal detection of the concentration of an analysis target.

[0310] Further, the rise part 226 and the fall part 227 of the detection signal are recognized, an interval between the rise part 226 and the fall part 227 is calculated, and the size of the interval is compared with a prescribed width of the detection part 83, thereby confirming the width of the detection part 83. Therefore, it is possible to judge whether the chromatography test strip is low in performance.

#### (Embodiment 15)

[0311] Hereinafter, a chromatography quantitative measuring apparatus that corresponds to the invention defined in Claims 40 to 43 of the present invention will be described as a fifteenth embodiment with reference to figure 17.

[0312] Figure 17 is a perspective view of the chromatography quantitative measuring apparatus according to the fifteenth embodiment.

[0313] In figure 17, numeral 1 denotes a light source, which emits a beam. Numeral 5 denotes a glass plate. Numeral 301 denotes a light receiving element, which receives a beam reflected at the glass plate 5. Numeral 302 denotes a light receiving element, which receives a beam that is transmitted through the glass plate 5 and reflected at the detection part 83 of an immuno-chromatography test strip 8. Numeral 8 denotes the immuno-chromatography test strip, which comprises a development layer 85 where an applied inspection target solution permeates and a carrier 86 that holds the development layer 85, and is approximately 50mm long by 5mm wide.

[0314] The development layer 85 comprises an application part 81 where the inspection target solution is applied, a marker reagent hold part 82 which has a marker reagent that specifically causes a binding reaction with a measurement target included in the inspection target

solution, a detection part 83 which has a reagent for immobilizing a specifically bounded material of the measurement target and the marker reagent, and a base part 84 which is located at a prescribed distance from the detection part 83 in order to avoid occurrence of an error in absorbance signal due to the bounded material that is not immobilized at the detection part 83. The development layer 85 is made of a membrane filter as a material that can be penetrated by the inspection target solution. In addition to the membrane filter, any arbitrary materials which can be penetrated by the inspection target solution, such as glass fiber filter paper and a non-woven fabric, can be employed as a material used for the development layer 85.

[0315] The carrier 86 is made of a PET (Polyethylene terephthalate) as a material which is not permeated by the inspection target solution. In addition to the PET, any arbitrary materials which is not penetrated by the inspection target solution, such as an ABS, can be employed as a material used for the carrier 86. By dropping an inspection target solution to the so-constituted immuno-chromatography test strip 8, a measurement target included in the inspection target solution can be measured.

[0316] Numeral 311 denotes a fixing table, which holds the immuno-chromatography test strip 8. The fixing table 311 can be used repeatedly at quantitative measurement, and the immuno-chromatography test strip 8 can be reattached thereto after a quantitative measurement. Thus, there is no necessity of a conventional hard case, thereby reducing the cost and minimizing a storage space for components required for the quantitative measurement.

[0317] Numeral 312 denotes a measurement table, which holds the fixing table 311. At this time, the measurement table 312 is provided with a groove for positioning the fixing table 311. Thereby, the fixing table 311 can be accurately attached to the measurement table 312. Further, by constructing the measurement table 312 so that it can be scanned, a quantitative measurement is performed by scanning a beam in the area down to the detection part 83 and the base part 84. Thereby, the absorbance signal at the detection part 83 and the base part 84 can be obtained. Here, the beam applied to the immuno-chromatography test strip 8 may be shaped circularly, elliptically, or rectangularly. Further, it is desirable that the beam is shaped so as to be applied to the whole detection part 83.

[0318] Numeral 313 denotes a fixing table carrier, which is movably attached to the measurement table 312 and employed to fix the fixing table 311 on the measurement table 312.

[0319] A description will be given of a quantitative measurement on the chromatography test strip 8 employing the so-configured chromatography quantitative measuring apparatus.

[0320] First, an inspection target solution is applied to the application part 81 of the immuno-chromatography

test strip 8. The applied inspection target solution is developed on the development layer 85. When a measurement target is included in the applied inspection target solution, at the marker reagent hold part 82, the measurement target included in the inspection target solution specifically causes a binding reaction with a marker reagent held at the marker reagent hold part 82. Then, the measurement target specifically bonded to the marker reagent, that is, a bounded material is immobilized at the detection part 83. At this time, discoloring reaction is caused with a width of approximately 1mm. The concentration at a discoloration part and the concentration of the measurement target are in proportion. The inspection target solution passing through the detection part 83 permeates the development layer 85 to be absorbed therein.

[0321] When the development of the inspection target solution is completed, a beam is emitted from the light source 1, and the emitted beam is input to the glass plate 5. The beam reflected at the glass plate 5 is input to the light receiving element 301 as a reference beam. On the other hand, the beam transmitted through the glass plate 5 is applied to the immuno-chromatography test strip 8. At this time, a scattering light generated on the surface of the development layer 85 is detected by the light receiving element 302. Then, the reference beam and the scattering light detected by the light receiving element 301 and the light receiving element 302 are respectively subjected to Log transformation, and the result of subtraction with these Log transformed values is obtained as an absorbance signal.

[0322] As described above, according to the chromatography quantitative measuring apparatus of the fifteenth embodiment, a measurement operation can be performed without the inspection target solution adhering to the chromatography quantitative measuring apparatus, and the immuno-chromatography test strip 8 can be easily attached to the chromatography quantitative measuring apparatus. Further, the beam can be accurately applied to the area down to the detection part 83 and the base part 84. Furthermore, a measurement can be performed solely with the immuno-chromatography test strip 8, so that there is no need to put the chromatography test strip 8 in a case individually, thereby reducing the cost for the casing and minimizing a storage space.

(Embodiment 16)

[0323] Hereinafter, a chromatography quantitative measuring apparatus that corresponds to the invention defined in Claims 44 to 53 of the present invention will be described as a sixteenth embodiment with reference to figure 18.

[0324] The difference from the fifteenth embodiment is that the carrier 86 and the fixing table 311 are provided with a hole 320 and a projection 321, respectively, so that the immuno-chromatography test strip 8 can be

easily and more accurately attached to the fixing table 311. The quantitative measuring method with the immuno-chromatography test strip 8 has been described with respect to the fifteenth embodiment, and a description thereof will be omitted here.

[0325] Figure 18 is a perspective view of the chromatography quantitative measuring apparatus according to the sixteenth embodiment. In the drawing, the same or corresponding constituent elements as those shown in figure 17 are denoted by the same reference numerals, and descriptions thereof will be omitted.

[0326] In figure 18, numeral 320 denotes the hole, which is provided in the carrier 86 of the immuno-chromatography test strip 8. While the hole 320 has a round shape, it may have a rectangular shape. When the hole 320 has a rectangular shape, a side or plural sides of the rectangle is employed for positioning of the immuno-chromatography test strip 8, so that it can be attached to the fixing table 311 more accurately. Further, when the hole 320 is provided in the carrier 86 at a position downstream in the direction in which the inspection target solution is developed, the inspection target solution is prevented from adhering to the hole 320 and the projection 321 during application of the inspection target solution. Furthermore, when the hole 320 is provided asymmetrically with respect to the center line of the immuno-chromatography test strip 8 in the longer-side direction, the immuno-chromatography test strip 8 is prevented from being erroneously attached to the fixing table 311 inside out.

[0327] Numeral 321 denotes the projection, which is provided on the fixing table 311 in the shape same as that of the hole 320 or a shape having a diameter slightly smaller than that of the hole 320. This projection 321 may be provided on the measurement table 312. In this case, as shown in figure 19, a hole with the shape same as that of the hole 320 is provided in the fixing table 311, and the projection 321 provided on the measurement table 312 penetrates the holes in the fixing table 311 and the carrier 86, so that the immuno-chromatography test strip 8 is easily attached to the fixing table 311 and accurately attached to the measurement table 312. At this time, it is desirable that the end of the projection 321 is inclined.

[0328] Numeral 322 denotes a guide for positioning the carrier 86, which is provided on the fixing table 311. The guide 322 is the same in width as the carrier 86 or slightly wider than the carrier 86. The immuno-chromatography test strip 8 is held on the fixing table 311 with the carrier 86 following the shape of the guide 322. Here, when the carrier 86 is larger than the development layer 85, it is the carrier 86 that gets contact with the guide 322, whereby the development layer 85 is prevented from being stripped off and adhering to the guide 322 in a detachment operation. Further, when the end faces of the guide 322 are inclined, the immuno-chromatography test strip 8 is easily attached to the fixing table 311.

[0329] As described above, according to the chroma-

tography measuring device of the sixteenth embodiment, the carrier 86 is larger than the development layer 85, so that it is the carrier 86 that gets contact with the guide 322, whereby it is possible to prevent the development layer 85 from being stripped off and adhering to the guide 322 in a detachment operation.

[0330] Further, the hole 320 is provided in the carrier 86 at a position downstream in the direction in which the inspection target solution is developed, and the projection 321 with the shape approximately same as that of the hole 320 and the guide 322 for fixing the carrier 86 are provided on the fixing table 311. Therefore, the development layer 85 is prevented from being stripped off and adhering to the projection 321. Further, the inspection target solution is prevented from adhering to the hole 320 and the projection 321 during application of the inspection target solution, whereby even when the immuno-chromatography test strip 8 is repeatedly attached to the fixing table 311, the accuracy of attachment is not deteriorated, and the immuno-chromatography test strip 8 can be easily and accurately attached to the fixing table 311.

[0331] In the sixteenth embodiment, also when a notch is provided in the carrier 86, and the shape of the guide 322 is the same as that of the notch provided in the carrier 86, so that the guide 322 is inserted in the notch, the immuno-chromatography test strip 8 can be accurately attached to the fixing table 311. At this time, when the notch is provided asymmetrically with respect to the center line of the immuno-chromatography test strip 8 in the longer-side direction, or the notch and the guide 322 are provided only on one side, the immuno-chromatography test strip 8 is prevented from being attached to the fixing table 311 inside out.

(Embodiment 17)

[0332] Hereinafter, a chromatography quantitative measuring apparatus that corresponds to the invention defined in Claims 54 to 62 of the present invention will be described as a seventeenth embodiment with reference to figures 20.

[0333] The difference from the sixteenth embodiment is that a test strip fixing device 323 that can be attached to the fixing table 311 is provided. The quantitative measurement on the immuno-chromatography test strip 8 has been described with respect to the fifteenth embodiment, and a description thereof will be omitted here.

[0334] Figures 20 are perspective views of the chromatography quantitative measuring apparatus according to the seventeenth embodiment. In the drawing, the same or corresponding constituent elements as those shown in figure 18 are denoted by the same reference numerals, and descriptions thereof will be omitted.

[0335] In figure 20(a), numeral 323 denotes the test strip fixing device, which presses a measurement area of the immuno-chromatography test strip 8 to smooth a part where a beam is applied, when it is attached to the

fixing table 311. Here, an area of the carrier 86 where the beam is scanned is pressed. Thereby, the development layer 85 is prevented from adhering to the test strip fixing device 323, and thus the accuracy of attachment of the test strip fixing device 323 can be maintained even when attachment and detachment thereof is repeated.

It is desirable that a part that gets contact with the carrier 86 has elasticity. While the test strip fixing device 323 and the fixing table 311 are different components, the test strip fixing device 323 may be integrated with the fixing table 311. By this configuration, it is possible to prevent a loss of the test strip fixing device 323.

[0336] Numeral 324 denotes a transmission window, through which a beam is transmitted. It is provided on the surface of the test strip fixing device 323 where the beam is applied, is slightly wider than the width of the beam, and is long enough in the longer-side direction not to prevent the beam from being scanned. Therefore, a measurement of absorbance can be performed while the test strip fixing device 323 is attached.

[0337] Numeral 325 denotes a pawl-shaped projection, which is provided in the test strip fixing device 323 to fix the test strip fixing device 323 on the fixing table 311. While a hole 340 in which the pawl-shaped projection 325 is inserted is provided in the fixing table 311, it is also possible that an interval between the two pawl-shaped projections 325 are made equal to the width of the fixing table 311, so that the test strip fixing device 323 is fixed.

[0338] Numeral 326 denotes a handle, which is provided in the test strip fixing device 323 to make it easy to attach/detach the test strip fixing device 323 to/from the fixing table 311. It is desired that the handle 326 has a shape which is easy for an operator to hold when he/she attaches/detaches the test strip fixing device 323 to/from the fixing table 311, and it is more desirable that the surface of the handle 326 is subjected to anti-slip processing.

[0339] Numeral 327 denotes a needle, which is provided in the test strip fixing device 323. When the test strip fixing device 323 is attached to the fixing table 311, the needle 327 penetrates the chromatography test strip 8, here, the carrier 86. Therefore, when the test strip fixing device 323 is detached from the fixing table 311, the immuno-chromatography test strip 8 is detached from the fixing table 311 with the test strip fixing device 323, whereby the immuno-chromatography test strip 8 can be disposed of without an inspection target solution adhering to an operator.

[0340] As described above, according to the chromatography quantitative measuring apparatus of the seventeenth embodiment, the immuno-chromatography test strip 8 is attached to the fixing table 311, and the test strip fixing device 323 having the transmission window 324 is attached thereto. Therefore, the area where the beam is scanned is smoothed, so that the accuracy of a measurement of absorbance is enhanced, and the measurement of absorbance can be performed while

the test strip fixing device 323 is attached.

[0341] Further, by bringing the test strip fixing device 323 into contact with the carrier 86, the development layer 85 is prevented from adhering to the test strip fixing device 323, and thus the accuracy of attachment of the test strip fixing device 323 can be maintained even when attachment and detachment thereof is repeated.

[0342] Furthermore, since the needle 327 is provided in the test strip fixing device 323, the immuno-chromatography test strip 8 is detached from the fixing table 311 with the test strip fixing device 323 when the test strip fixing device 323 is detached from the fixing table 311, whereby it is possible to dispose of the immuno-chromatography test strip 8 without an inspection target solution adhering to an operator.

[0343] While in the seventeenth embodiment the description has been given of the case where the test strip fixing device 323 is attached to the fixing table 311 employing the pawl-shaped projections 325 as shown in figure 20(a), the test strip fixing device 323 may be attached to the fixing table 311 by sliding the test strip fixing device 323 along the fixing table 311, as shown in figure 20(b). At this time, the test strip fixing device 323 and the fixing table 311 are fixed by taking the shape of wedge. Further, it is also possible that an inclination part is provided in the test strip fixing device 323 or the fixing table 311, so that the test strip fixing device 323 and the fixing table 311 are brought into contact at this inclination part, thereby fixing the test strip fixing device 323 on the fixing table 311.

#### (Embodiment 18)

[0344] Hereinafter, a chromatography quantitative measuring apparatus that corresponds to the invention defined in Claims 63 to 68 of the present invention will be described as an eighteenth embodiment with reference to figure 21.

[0345] The difference from the fifteenth embodiment is that the carrier 86 and the fixing table 311 are provided with grooves 328 and a guide 329, respectively. The quantitative measurement on the immuno-chromatography test strip 8 has been described with respect to the fifteenth embodiment, and a description thereof will be omitted here.

[0346] Figure 21 is a cross sectional view of the chromatography quantitative measuring apparatus according to the eighteenth embodiment. In the drawing, the same or corresponding constituent elements as those shown in figure 17 are denoted by the same reference numerals, and descriptions thereof will be omitted.

[0347] In figure 21, the immuno-chromatography test strip 8 is provided with a notch 350 at its end on the side of insertion into the fixing table 311. When the notch 350 is provided asymmetrically with respect to the center line of the immuno-chromatography test strip 8 in the longer-side direction, it is possible to prevent a failure such as inside-out attachment of the immuno-chromatography

test strip 8.

[0348] The carrier 86 is provided with the grooves 328. When the grooves 328 are formed by a laser cutter which is employed when the immuno-chromatography test strip 8 is formed, process of operation can be omitted. At this time, it is desired that the grooves 328 and the guide 329 are provided asymmetrically with respect to the center line of the immuno-chromatography test strip 8 in the longer-side direction.

[0349] The fixing table 311 is provided with a projection 330 having the shape same as that of the notch 350, the guide 329 which can be inserted in the grooves 328, and an insertion slot in which the immuno-chromatography test strip 8 can be inserted. Here, the insertion slot is inclined so as to become narrower toward the interior of the fixing table 311.

[0350] As described above, according to the chromatography quantitative measuring apparatus of the eighteenth embodiment, the immuno-chromatography test strip 8 can be fixed in the fixing table 311 at a prescribed position. At this time, since the notch 350 provided in the carrier 86 is provided asymmetrically with respect to the center line of the immuno-chromatography test strip 8 in the longer-side direction, the immuno-chromatography test strip 8 can be prevented from being attached inside out.

#### (Embodiment 19)

[0351] Hereinafter, a chromatography quantitative measuring apparatus that corresponds to the invention defined in Claims 69 to 77 of the present invention will be described as a nineteenth embodiment with reference to figures 22.

[0352] The difference from the fifteenth embodiment is that the carrier 86 and the fixing table 311 are provided with the groove 328 and the guide 329, respectively. The quantitative measurement on the immuno-chromatography test strip 8 has been described with respect to the fifteenth embodiment, and a description thereof will be omitted here.

[0353] Figures 22 are perspective views of the chromatography quantitative measuring apparatus according to the nineteenth embodiment. In the drawings, the same or corresponding constituent elements as those shown in figure 21 are denoted by the same reference numerals, and descriptions thereof will be omitted.

[0354] In figure 22(a), the carrier 86 is provided with the groove 328 at its end on the side of insertion into the fixing table 311.

[0355] The fixing table 311 is provided with the guide 329 which can be inserted in the groove 328, and a holding member 331 for pressing the immuno-chromatography test strip 8, which is made of an elastic member.

[0356] When the immuno-chromatography test strip 8 is completely inserted in the fixing table 311, the guide 329 is inserted in the groove 328, so that the immuno-chromatography test strip 8 is fixed in the fixing table

311 at a prescribed position. At this time, when there is provided a means for detecting the insertion of the guide 329 into the groove 328, it is possible to recognize that the immuno-chromatography test strip 8 is correctly disposed in the fixing table, whereby erroneous measurement operation can be prevented. As an example, there is a configuration in which the guide 329 is provided with an electrode and the surface of the groove 328 is covered with a conductive material.

[0357] The holding member 331 is integrated with the fixing table 311 and presses the vicinity of an area on the immuno-chromatography test strip 8 where a beam is scanned. Specifically, it is desired that a part of the carrier 86 is pressed, and the end of the holding member 331 is inclined. The immuno-chromatography test strip 8 inserted in the fixing table 311 is positioned as the end of the carrier 86 is introduced with walls of the fixing table 311 as a guide. It is desired that there is provided a mechanism for releasing the holding member 331 in a process for removing the immuno-chromatography test strip 8 from the fixing table 311. The holding member 331 may not be necessarily integrated with the fixing table 311 and may be provided in the chromatography quantitative measuring apparatus. In this case, it is desirable that the holding member 331 is detachable.

[0358] While the position of the immuno-chromatography test strip 8 is decided by employing the groove 328 and the guide 329 in figure 22(a), the position may be decided by the carrier 86 whose width on the insertion side is narrowed to form stages, as shown in figure 22(b).

[0359] As described above, according to the chromatography quantitative measuring apparatus of the nineteenth embodiment, since the holding member 331 for pressing the carrier 86 is provided, an area where a beam is scanned can be smoothed, thereby enhancing the accuracy of a measurement of absorbance. At this time, since the end of the holding member 331 is inclined, the holding member 331 is easily attached/detached to/from the fixing table 311.

(Embodiment 20)

[0360] Hereinafter, a chromatography quantitative measuring apparatus that corresponds to the invention defined in Claims 78 to 88 of the present invention will be described as a twentieth embodiment with reference to figures 23 and 24.

[0361] The quantitative measurement on the immuno-chromatography test strip 8 has been described with respect to the fifteenth embodiment, and a description thereof will be omitted here.

[0362] Figure 23 is a perspective views of the chromatography quantitative measuring apparatus according to the twentieth embodiment. In the drawing, the same or corresponding constituent elements as those shown in figure 17 are denoted by the same reference numerals, and descriptions thereof will be omitted.

[0363] In figure 23, an operator holds the carrier 86 and detaches the immuno-chromatography test strip from the fixing table. Thereby, it is possible to prevent the operator from being contaminated with a sample when detaching the immuno-chromatography test strip 8. At this time, as shown in figure 23, the carrier 86 is bent and the end thereof is in the air, so that the operator can hold this bent part. At this time, the part of the carrier 86 which is to be held is provided with a slip stopper 332. Therefore, the operator can easily hold the bent part when detaching the immuno-chromatography test strip 8, resulting in enhancement in operability. While the slip stopper 332 is provided in the shape of projections, the slip stopper 332 may take the shape of grooves or shape obtained by knurling processing on the surface of the carrier 86. Here, when a groove is previously provided at a part where a valley is to be made when the carrier 86 is bent, the carrier 86 can be bent easily, thereby detaching the immuno-chromatography test strip 8 easily. Further, when the part of the carrier 86 which is to be held protrudes above the fixing table 311, the operator can hold the part easily, resulting in enhancement in operability.

[0364] The fixing table 311 is provided with a saucer 333 which is a groove for receiving an inspection target solution, and an aperture of this saucer 333 is larger than the carrier 86. Further, the saucer 333 is provided with a slope 334, so that the inspection target solution can be applied not only to the application part 81 of the immuno-chromatography test strip 8 from above but also to the development layer 85 from the cross sectional direction. When the surface of the fixing table 311 is subjected to water repellent finishing, a sample which erroneously escapes during the application of sample to the immuno-chromatography test strip 8 can be easily wiped. Further, since an absorbent material 335 as an absorbent substance is attached to the saucer 333 of the fixing table, the sample which erroneously escapes during the application of sample is absorbed by the absorbent material 335, so that the sample is prevented from adhering to the chromatography quantitative measuring apparatus. The absorbent material 335 is provided on the bottom surface of the saucer 333 and is replaceable.

[0365] Further, as shown in figure 24, when the fixing table 311 is provided with a through hole 336 at a part that gets contact with the carrier 86, so that a removal bar 337 is inserted in the through hole 336, the immuno-chromatography test strip 8 can be easily removed from the fixing table 311. The removal bar 337 may be integrated with the fixing table 311.

[0366] As described above, according to the chromatography quantitative measuring apparatus of the twentieth embodiment, it is possible to prevent the inspection target solution from adhering to an operator when the operator detaches the immuno-chromatography test strip 8 on which a measurement is finished from the fixing table 311. Here, since the fixing table 311 is subject-

ed to water repellent finishing, an inspection target solution that erroneously adheres to the fixing table 311 is easily wiped. Further, since the slope 334 is provided, even when a different method of applying the inspection target solution is employed, the fixing table 311 is applicable thereto without being replaced.

#### APPLICABILITY IN INDUSTRY

[0367] A chromatography quantitative measuring apparatus according to the present invention has a high accuracy of a quantitative measurement, and is available as a chromatography quantitative measuring apparatus for a measurement employing an immuno-chromatography test strip or the like.

#### Claims

1. A chromatography quantitative measuring apparatus which applies a beam emitted from a light source to a sample, detects an optical signal from a transmitted light or reflected light from the sample, and quantitatively reads the concentration of the sample from the signal, including:

an optical means for forming the beam emitted from the light source into an elliptical or rectangular shape and applying the elliptically or rectangularly shaped beam to the sample.

2. The chromatography quantitative measuring apparatus as defined in Claim 1, wherein
  - the sample is put on an immuno-chromatography test strip, and
  - the beam applied to the sample has a longer side which is shorter than the width of the immuno-chromatography test strip in the width direction that is orthogonal with respect to the long-side direction.

3. The chromatography quantitative measuring apparatus as defined in Claim 1, wherein
  - the sample is put on an immuno-chromatography test strip, and
  - the beam applied to the sample has a shorter side which is shorter than the width of a detection part region of the immuno-chromatography test strip.

4. The chromatography quantitative measuring apparatus as defined in any of Claims 1 to 3, wherein
  - the optical signal is detected by scanning the beam applied to the sample, or the sample.

5. The chromatography quantitative measuring apparatus as defined in Claim 1, wherein
  - a laser is used as the light source, and a laser beam from the light source is converted into a col-

limated beam via a collimator lens, and  
the optical means forms the collimated beam into an elliptical shape via a cylindrical lens and applies the elliptically shaped beam to the sample.

6. The chromatography quantitative measuring apparatus as defined in Claim 1, wherein

a laser is used as the light source, and the laser beam from the light source is converted into a collimated beam via a collimator lens, and

the optical means forms the collimated beam into a rectangular shape via a rectangularly shaped aperture member and applies the rectangularly shaped beam to the sample.

7. A chromatography quantitative measuring apparatus which applies a beam emitted from a light source to a sample, detects an optical signal from a transmitted light or reflected light from the sample, and quantitatively reads the concentration of the sample from the signal, including:

a laser as the light source; and  
a collimator lens which converts the laser beam into a collimated beam, wherein

when the collimated beam is shaped rectangularly via an aperture member and the rectangularly shaped beam is applied to the sample, the direction of a longer side of the rectangularly shaped beam is made to correspond to the direction in which the beam divergence angle of the laser becomes larger.

8. A chromatography quantitative measuring apparatus which applies a beam emitted from a light source to a sample, detects an optical signal from a transmitted light or reflected light from the sample, and quantitatively reads the concentration of the sample from the signal, including:

a laser as the light source; and  
a collimator lens which converts the laser beam into a collimated beam, wherein

when the collimated beam is shaped elliptically via a cylindrical lens and the elliptically shaped beam is applied to the sample, the direction of a longer side of the elliptically shaped beam is made to correspond to the direction in which the beam divergence angle of the laser becomes larger.

9. The chromatography quantitative measuring apparatus as defined in any of Claims 5 to 8, including:

a compensation means for storing the initial wavelength of the laser, calculating the present wavelength of the laser to compensate by pro-

- vision of a temperature detection element in the vicinity of the laser, and compensating an optical signal detection value or the converted concentration of the sample which is obtained by converting the optical signal detection value. 5
10. The chromatography quantitative measuring apparatus as defined in Claim 9, wherein the compensation means performs processing for detecting the optical signal, processing for obtaining the converted concentration of the sample, and processing for compensating the converted concentration, with the same calculator. 10
11. The chromatography quantitative measuring apparatus as defined in any of Claims 5 to 8, wherein the concentration of the sample is calculated from a difference between electronic signals obtained by two light receiving elements, i.e., a reference beam light receiving element which receives a reference beam separated from the beam emitted from the laser, and a scattering light receiving element which receives a scattering light generated by the application of the laser to the sample, and the area of the reference beam light receiving element for receiving light is smaller than the area of the scattering light receiving element for receiving light. 15 20 25
12. The chromatography quantitative measuring apparatus as defined in any of Claims 5 to 8, wherein the concentration of the sample is calculated from a difference between electronic signals obtained by two light receiving elements, i.e., a reference beam light receiving element which receives a reference beam separated from the beam emitted from the laser, and a scattering light receiving element which receives a scattering light generated by the application of the laser to the sample, including: 30 35 40
- a condensing means for condensing the scattering light from the sample on the scattering light receiving element.
13. The chromatography quantitative measuring apparatus as defined in Claim 12, wherein the condensing means is a concave mirror which condenses a light from the sample that is scattered in the opposite direction of the direction in which the scattering light receiving element is arranged, on the scattering light receiving element. 45 50
14. The chromatography quantitative measuring apparatus as defined in Claim 12, wherein the condensing means is a condensing lens arranged between the sample and the scattering light receiving element, which condenses the scattering light from the sample that goes toward the 55
- scattering light receiving element, on the scattering light receiving element.
15. A chromatography quantitative measuring apparatus which applies an optical beam emitted from a light source to a chromatography test strip that comprises an application part where an inspection target solution is applied; a marker reagent hold part which holds a marker reagent that can be eluted by development of the inspection target solution; a base part where a specific binding reaction is caused between the marker reagent and an analysis target included in the inspection target solution; and a detection where a bounded material of the marker reagent and the analysis target is immobilized, detects an optical signal utilizing a transmitted light or reflected light from the chromatography test strip, and quantitatively measures the concentration of the analysis target included in the inspection target solution from the signal, wherein the inspection target solution is applied to the chromatography test strip, the optical beam is applied to a prescribed position of the base part, a variation of the transmitted light or reflected light from the chromatography test strip, which is generated by the elution of the marker reagent that accompanies the development of the inspection target solution, is detected, and the concentration of the analysis target included in the inspection target solution is measured in a prescribed period of time since the detection of variation.
16. The chromatography quantitative measuring apparatus as defined in Claim 15, wherein at least one of temperature and humidity is monitored, and a previously set prescribed period of time after which the measurement of the concentration of the analysis target is performed is compensated.
17. The chromatography quantitative measuring apparatus as defined in Claim 15, wherein the light source is repeatedly lighted and extinguished alternately while the development of the inspection target solution is detected.
18. The chromatography quantitative measuring apparatus as defined in Claim 15, wherein the light source is extinguished until shortly before the detection of the development of the inspection target solution.
19. The chromatography quantitative measuring apparatus as defined in Claim 15, wherein output from the light source is set lower than that when the concentration of the analysis target is measured, while the development of the inspection target solution is detected.



20. A chromatography quantitative measuring apparatus which applies an optical beam emitted from a light source to a chromatography test strip that comprises an application part where an inspection target solution is applied; a marker reagent hold part which holds a marker reagent that can be eluted by development of the inspection target solution; a base part where a specific binding reaction is caused between the marker reagent and an analysis target included in the inspection target solution; and a detection part where a bounded material of the marker reagent and the analysis target is immobilized, detects an optical signal utilizing a transmitted light or reflected light from the chromatography test strip, and quantitatively measures the concentration of the analysis target included in the inspection target solution from the signal, wherein  
the inspection target solution is applied to the chromatography test strip, a speed of development after the application of the inspection target solution is detected, and it is judged whether performance of the chromatography test strip is high or low from the speed of development.
21. The chromatography quantitative measuring apparatus as defined in Claim 20, wherein  
the speed of development is calculated by detecting time variation of value of a detection signal, which is generated by the flow of the marker reagent that accompanies the development of the inspection target solution on the chromatography test strip.
22. The chromatography quantitative measuring apparatus as defined in Claim 20, wherein  
the speed of development is calculated from a speed of scanning of the optical beam, when the optical beam is scanned so that a value of the detection signal, which is generated by the elution of the marker reagent that accompanies the development of the inspection target solution on the chromatography test strip, is kept constant.
23. The chromatography quantitative measuring apparatus as defined in Claim 20, wherein  
a discrimination value of the speed of development, from which whether performance of the chromatography test strip is high or low is judged, is compensated from a result of measuring at least one of surrounding temperature and humidity at the development of the inspection target solution on the chromatography test strip.
24. A chromatography quantitative measuring apparatus which applies an optical beam emitted from a light source to a chromatography test strip that comprises an application part where an inspection target solution is applied; a marker reagent hold part which holds a marker reagent that can be eluted by development of the inspection target solution; a base part where a specific binding reaction is caused between the marker reagent and an analysis target included in the inspection target solution; and a detection part where a bounded material of the marker reagent and the analysis target is immobilized, detects an optical signal utilizing a transmitted light or reflected light from the chromatography test strip, and quantitatively measures the concentration of the analysis target included in the inspection target solution from the signal, wherein  
a kind of inspection target solution is judged from a detection signal at the base part on the chromatography test strip where the inspection target solution is applied.
25. The chromatography quantitative measuring apparatus as defined in Claim 24, wherein  
the base part where the detection signal is measured is located downstream of the detection part in the direction of the development.
26. The chromatography quantitative measuring apparatus as defined in Claim 24, wherein  
a calibration curve in conformity with the inspection target solution can be selected previously.
27. A chromatography quantitative measuring apparatus which applies an optical beam emitted from a light source to a chromatography test strip that comprises an application part where an inspection target solution is applied; a marker reagent hold part which holds a marker reagent that can be eluted by development of the inspection target solution; a base part where a specific binding reaction is caused between the marker reagent and an analysis target included in the inspection target solution; and a detection part where a bounded material of the marker reagent and the analysis target is immobilized, detects an optical signal utilizing a transmitted light or reflected light from the chromatography test strip, and quantitatively measures the concentration of the analysis target included in the inspection target solution from the signal, wherein  
deficiency in the amount of inspection target solution applied and insufficient development on the chromatography test strip are judged from a detection signal that is obtained by applying the optical beam to the downstream end part of the base part on the chromatography test strip where the inspection target solution is applied.
28. The chromatography quantitative measuring apparatus as defined in Claim 27, wherein  
the optical beam is scanned from the upstream end part of the base part on the chromatography test strip to the downstream end part thereof.

29. A chromatography quantitative measuring apparatus which applies an optical beam emitted from a light source to a chromatography test strip that comprises an application part where an inspection target solution is applied; a marker reagent hold part which holds a marker reagent that can be eluted by development of the inspection target solution; a base part where a specific binding reaction is caused between the marker reagent and an analysis target included in the inspection target solution; and a detection part where a bounded material of the marker reagent and the analysis target is immobilized, detects an optical signal utilizing a transmitted light or reflected light from the chromatography test strip, and quantitatively measures the concentration of the analysis target included in the inspection target solution from the signal, wherein

when a detection signal at a part downstream of the detection part in the direction of the development, where influence of the detection part is not exerted, is a standard value, a detection signal at the detection part is taken as a detection signal for the measurement of concentration.

30. The chromatography quantitative measuring apparatus as defined in Claim 29, wherein

the detection signal for the measurement of concentration is an average value of values about an extreme value of the detection part, and the detection signal as the standard value is an average value of values in the vicinity of the position downstream of the detection part in the direction in which the inspection target solution is developed, where influence of the detection part is not exerted.

31. The chromatography quantitative measuring apparatus as defined in Claim 29, wherein

the detection signal for the measurement of concentration is an intermediate value of values about an extreme value of the detection part, and the detection signal as the standard value is an intermediate value of values in the vicinity of the position downstream of the detection part in the direction in which the inspection target solution is developed, where influence of the detection part is not exerted.

32. The chromatography quantitative measuring apparatus as defined in Claim 29, wherein

a comparison is made of values about an extreme value of the detection signal at the detection part, and when a difference therebetween exceeds a discrimination value, the chromatography test strip is judged to be low in performance.

33. The chromatography quantitative measuring apparatus as defined in Claim 29, wherein

a comparison is made of values in the vicinity

of a position downstream of the detection part in the direction of the development, where influence of the detection part is not exerted, and when a difference therebetween exceeds a discrimination value, the chromatography test strip is judged to be low in performance.

34. A chromatography quantitative measuring apparatus which applies an optical beam emitted from a light source to a chromatography test strip that comprises an application part where an inspection target solution is applied; a marker reagent hold part which holds a marker reagent that can be eluted by development of the inspection target solution; a base part where a specific binding reaction is caused between the marker reagent and an analysis target included in the inspection target solution; and a detection part where a bounded material of the marker reagent and the analysis target is immobilized, detects an optical signal utilizing a transmitted light or reflected light from the chromatography test strip, and quantitatively measures the concentration of the analysis target included in the inspection target solution from the signal, wherein

the measurement of concentration is performed on the chromatography test strip exclusive of the marker reagent hold part.

35. A chromatography quantitative measuring apparatus which applies an optical beam emitted from a light source to a chromatography test strip that comprises an application part where an inspection target solution is applied; a marker reagent hold part which holds a marker reagent that can be eluted by development of the inspection target solution; a base part where a specific binding reaction is caused between the marker reagent and an analysis target included in the inspection target solution; and a detection part where a bounded material of the marker reagent and the analysis target is immobilized, detects an optical signal utilizing a transmitted light or reflected light from the chromatography test strip, and quantitatively measures the concentration of the analysis target included in the inspection target solution from the signal, wherein

a region on the chromatography test strip where a value of the detection signal is flat is taken as a region of the marker reagent hold part.

36. The chromatography quantitative measuring apparatus as defined in Claim 35, wherein

the width of the region on the chromatography test strip where the value of the detection signal is flat is calculated, and the width is compared with a prescribed width of the marker reagent hold part.

37. The chromatography quantitative measuring apparatus as defined in Claim 35, wherein

a value in the region on the chromatography test strip where the detection signal is flat is detected, and the amount of residual marker reagent is confirmed from the detected value.

38. A chromatography quantitative measuring apparatus which applies an optical beam emitted from a light source to a chromatography test strip that comprises an application part where an inspection target solution is applied; a marker reagent hold part which holds a marker reagent that can be eluted by development of the inspection target solution; a base part where a specific binding reaction is caused between the marker reagent and an analysis target included in the inspection target solution; and a detection part where a bounded material of the marker reagent and the analysis target is immobilized, detects an optical signal utilizing a transmitted light or reflected light from the chromatography test strip, and quantitatively measures the concentration of the analysis target included in the inspection target solution from the signal, wherein

a rise and fall of a detection signal are recognized, and an extreme value of the detection signal is obtained.

39. The chromatography quantitative measuring apparatus as defined in Claim 38, wherein the rise and fall of the detection signal is recognized, an interval between the rise and the fall is calculated, and the size of the interval is compared with a prescribed width of the detection part.

40. A chromatography quantitative measuring apparatus for performing a quantitative measurement by applying an inspection target solution to an immuno-chromatography test strip, applying a beam to a detection part of the immuno-chromatography test strip after development of the inspection target solution, so as to detect an optical signal, and quantitatively reading the concentration of a sample from the detected signal, including:

a fixing table for holding the immuno-chromatography test strip and a measurement table for holding the fixing table, wherein the immuno-chromatography test strip comprises a development layer for developing the inspection target solution and a carrier for holding the development layer.

41. The chromatography quantitative measuring apparatus as defined in Claim 40, wherein the measurement table is provided with a groove for positioning the fixing table.

42. The chromatography quantitative measuring apparatus as defined in Claim 40, wherein

the measurement table is provided with a movable projection for fixing the fixing table.

43. The chromatography quantitative measuring apparatus as defined in Claim 40, wherein the quantitative measurement is performed by scanning the beam.

44. The chromatography quantitative measuring apparatus as defined in Claim 40, wherein the fixing table is provided with a projection, and the carrier is provided with a hole in which the projection can be inserted.

45. The chromatography quantitative measuring apparatus as defined in Claim 44, wherein the hole has a round shape.

46. The chromatography quantitative measuring apparatus as defined in Claim 44, wherein the hole has a rectangular shape.

47. The chromatography quantitative measuring apparatus as defined in Claim 44, wherein the hole is provided downstream of the development layer in the direction in which the inspection target solution is developed.

48. The chromatography quantitative measuring apparatus as defined in Claim 44, wherein the hole is provided asymmetrically with respect to the center line of the immuno-chromatography test strip in the longer-side direction.

49. The chromatography quantitative measuring apparatus as defined in Claim 40, wherein the fixing table is provided with a guide, and the carrier is larger than the development layer and follows the shape of the guide.

50. The chromatography quantitative measuring apparatus as defined in Claim 49, wherein a part of the guide is inclined.

51. The chromatography quantitative measuring apparatus as defined in Claim 49, wherein the carrier is provided with a notch in which the guide can be inserted.

52. The chromatography quantitative measuring apparatus as defined in Claim 40, wherein the measurement table is provided with a projection, and the immuno-chromatography test strip and the fixing table are provided with holes in which the projection can be inserted.

53. The chromatography quantitative measuring apparatus as defined in Claim 52, wherein the projection has its end inclined.
54. The chromatography quantitative measuring apparatus as defined in Claim 40, including:
- a test strip fixing device for fixing the immuno-chromatography test strip on the fixing table, wherein
- the test strip fixing device presses the vicinity of a measurement area of the immuno-chromatography test strip.
55. The chromatography quantitative measuring apparatus as defined in Claim 54, wherein the test strip fixing device presses the carrier of the immuno-chromatography test strip.
56. The chromatography quantitative measuring apparatus as defined in Claim 54, wherein the test strip fixing device is provided with a transmission window through which the beam is transmitted.
57. The chromatography quantitative measuring apparatus as defined in Claim 54, wherein the test strip fixing device is provided with pawl-shaped projections for fixing the test strip fixing device on the fixing table.
58. The chromatography quantitative measuring apparatus as defined in Claim 54, wherein the test strip fixing device slides along the fixing table.
59. The chromatography quantitative measuring apparatus as defined in Claim 58, wherein the test strip fixing device or the fixing table is provided with an inclination part, and the test strip fixing device and the fixing table are brought into contact at the inclination part, thereby fixing the test strip fixing device on the fixing table.
60. The chromatography quantitative measuring apparatus as defined in Claim 54, wherein the test strip fixing device is integrated with the fixing table.
61. The chromatography quantitative measuring apparatus as defined in Claim 54, wherein the test strip fixing device is provided with handles.
62. The chromatography quantitative measuring apparatus as defined in Claim 54, wherein the test strip fixing device is provided with a
- needle which penetrates the immuno-chromatography test strip.
63. The chromatography quantitative measuring apparatus as defined in Claim 40, wherein the carrier is provided with grooves, and the fixing table or the measurement table is provided with a guide which can be inserted in the grooves.
64. The chromatography quantitative measuring apparatus as defined in Claim 63, wherein the grooves are formed by a laser cutter.
65. The chromatography quantitative measuring apparatus as defined in Claim 40, wherein the fixing table is provided with an insertion slot in which the immuno-chromatography test strip can be inserted.
66. The chromatography quantitative measuring apparatus as defined in Claim 65, wherein the insertion slot is inclined.
67. The chromatography quantitative measuring apparatus as defined in Claim 65, wherein the immuno-chromatography test strip is provided with a notch at its end on the side of insertion into the fixing table, and the fixing table is provided with a projection which has the shape same as that of the notch.
68. The chromatography quantitative measuring apparatus as defined in Claim 67, wherein the notch is provided asymmetrically with respect to the center line of the immuno-chromatography test strip in the longer-side direction.
69. The chromatography quantitative measuring apparatus as defined in Claim 65, wherein the carrier is provided with a groove at its end on the side of insertion of the immuno-chromatography test strip into the fixing table, and the fixing table is provided with a projection which can be inserted in the groove.
70. The chromatography quantitative measuring apparatus as defined in Claim 69, including:
- a means for detecting whether the projection is inserted in the groove.
71. The chromatography quantitative measuring apparatus as defined in Claim 65, wherein the immuno-chromatography test strip is shaped to have stages by narrowing the width on the side of insertion into the fixing table.

72. The chromatography quantitative measuring apparatus as defined in Claim 65, wherein the fixing table is provided with an elastic member for pressing the immuno-chromatography test strip. 5
73. The chromatography quantitative measuring apparatus as defined in Claim 72, wherein the elastic member is integrated with the fixing table. 10
74. The chromatography quantitative measuring apparatus as defined in Claim 72, wherein the elastic member has its end inclined. 15
75. The chromatography quantitative measuring apparatus as defined in Claim 72, including:  
a mechanism for releasing the press by the elastic member. 20
76. The chromatography quantitative measuring apparatus as defined in Claim 40, including:  
an elastic member for pressing the immuno-chromatography test strip. 25
77. The chromatography quantitative measuring apparatus as defined in Claim 72 or 76, wherein the elastic member is detachable. 30
78. The chromatography quantitative measuring apparatus as defined in Claim 40, wherein an operator can hold the carrier to detach the immuno-chromatography test strip from the fixing table. 35
79. The chromatography quantitative measuring apparatus as defined in Claim 78, wherein the carrier is bent to create a space between the fixing table and the end of the carrier. 40
80. The chromatography quantitative measuring apparatus as defined in Claim 79, wherein the carrier is provided with a groove to be bent therealong. 45
81. The chromatography quantitative measuring apparatus as defined in Claim 78, wherein the carrier protrudes above the fixing table. 50
82. The chromatography quantitative measuring apparatus as defined in Claim 78, wherein a part of the carrier is provided with a slip stopper. 55
83. The chromatography quantitative measuring apparatus as defined in Claim 40, wherein the fixing table is provided with a groove for receiving the inspection target solution.
84. The chromatography quantitative measuring apparatus as defined in Claim 83, wherein the groove is given a slope, so that the inspection target solution can be supplied to the development layer from the direction of the cross section of the immuno-chromatography test strip.
85. The chromatography quantitative measuring apparatus as defined in Claim 40, wherein the fixing table is subjected to water repellent finishing.
86. The chromatography quantitative measuring apparatus as defined in Claim 40, wherein the fixing table is attached with an absorbent material.
87. The chromatography quantitative measuring apparatus as defined in Claim 40, wherein the fixing table has a through hole in which a removal bar can be inserted, and the bar is inserted in the through hole to press the immuno-chromatography test strip, thereby removing the immuno-chromatography test strip from the fixing table.
88. The chromatography quantitative measuring apparatus as defined in Claim 87, wherein the removal bar is integrated with the fixing table.

Fig.1 (a)

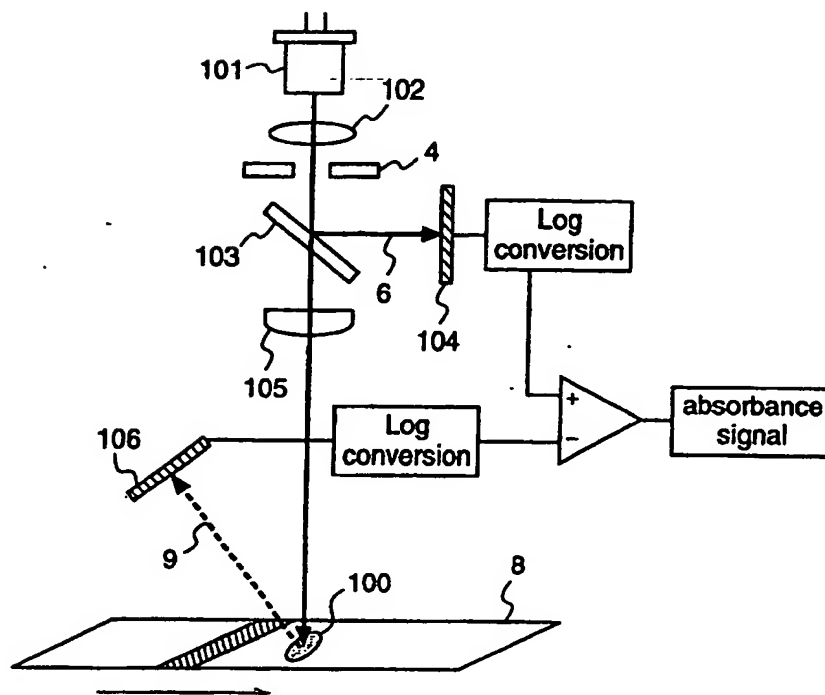


Fig.1 (b)

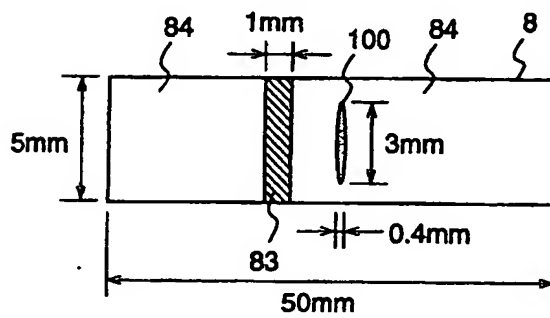


Fig.2 (a)

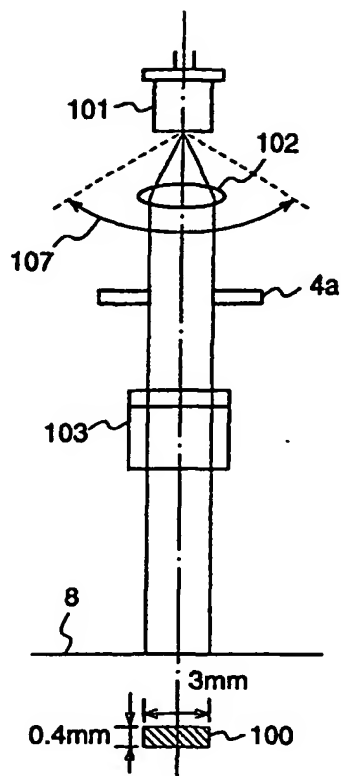


Fig.2 (b)

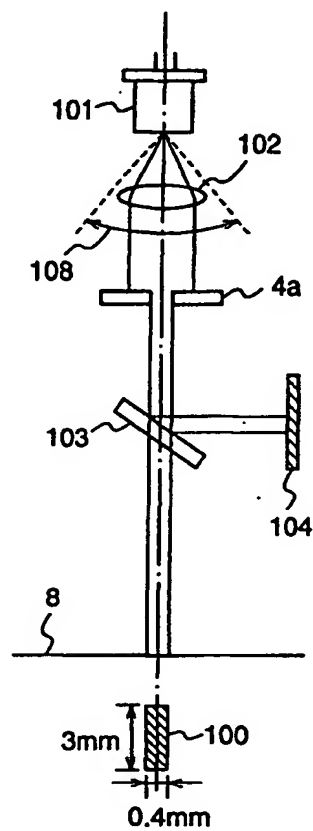




Fig.3 (a)

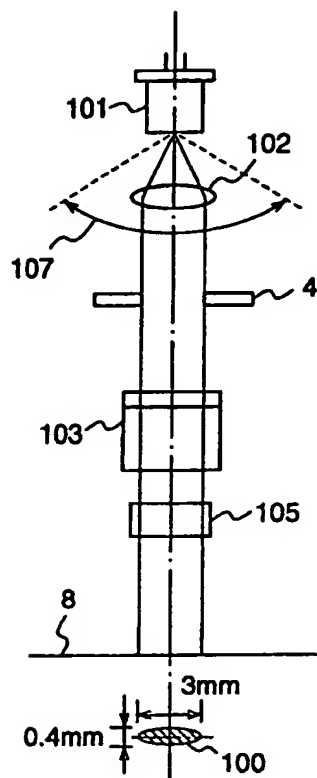


Fig.3 (b)

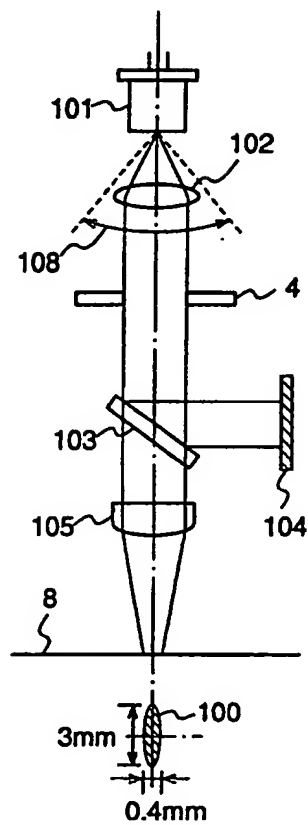


Fig.4

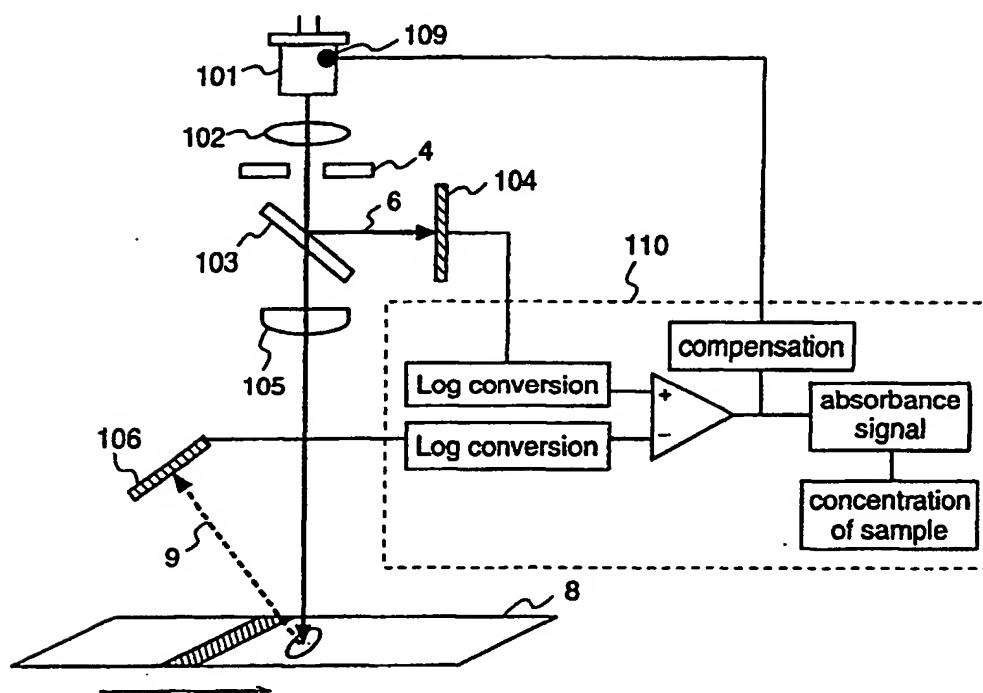


Fig.5

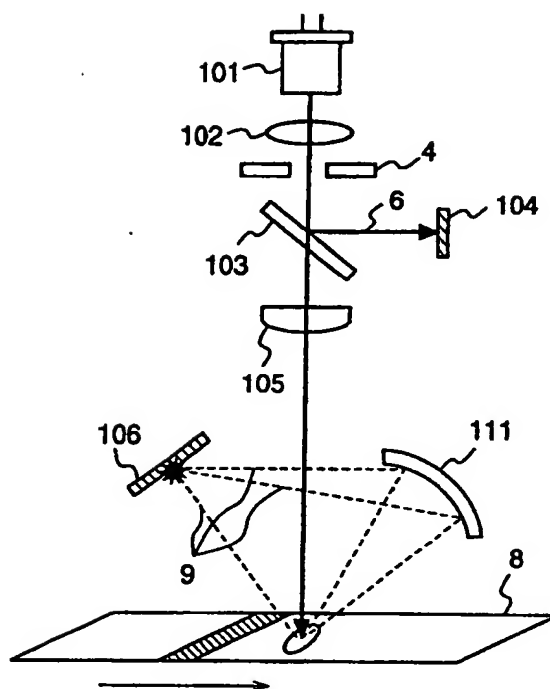


Fig.6

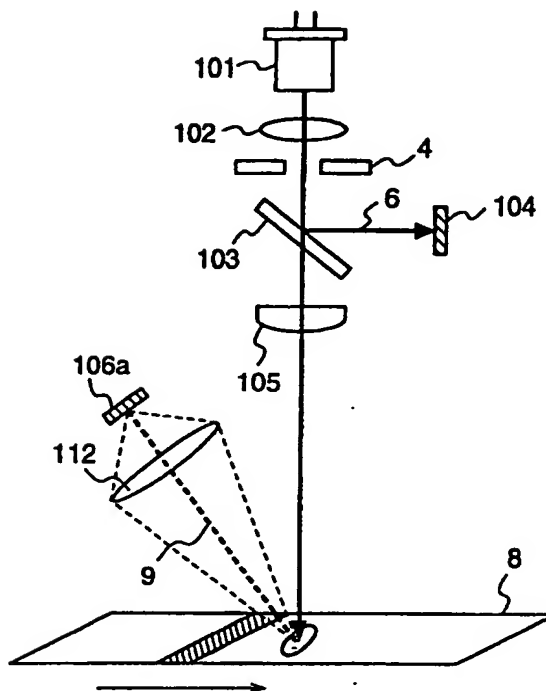


Fig.7 (a)

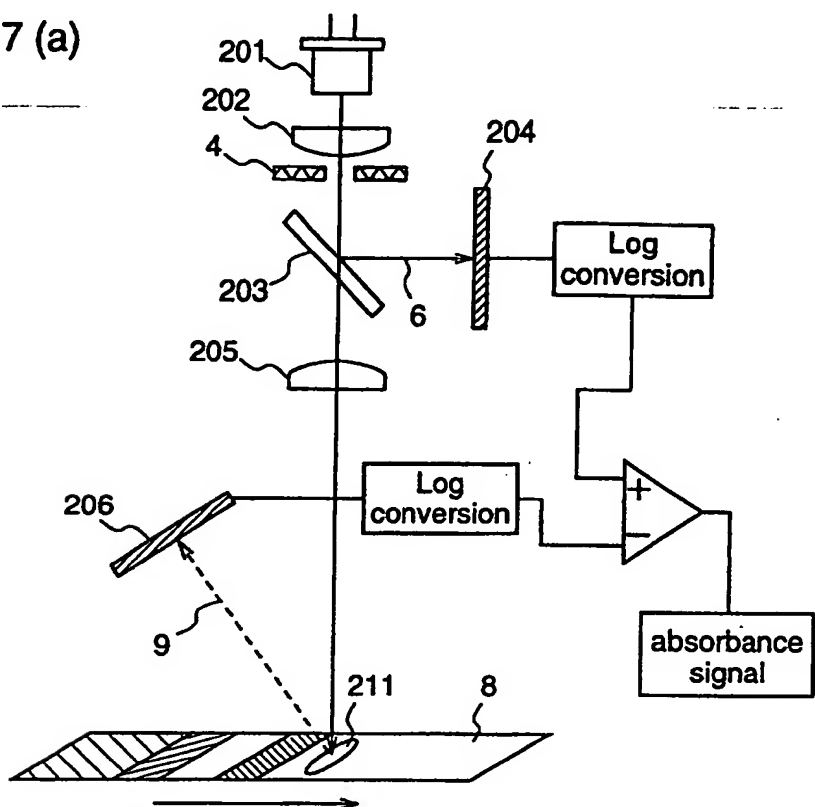


Fig.7 (b)

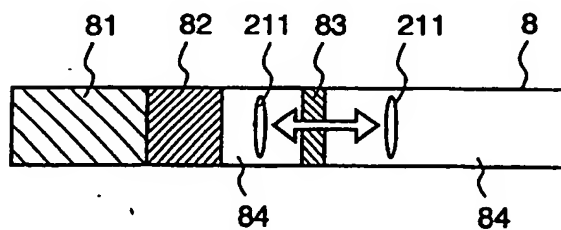


Fig.8 (a)

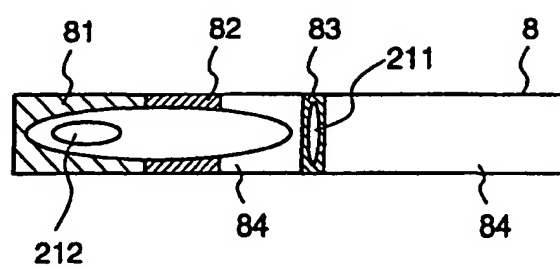


Fig.8 (b)

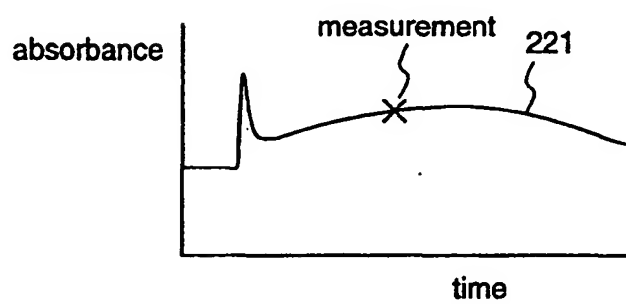


Fig.9 (a)

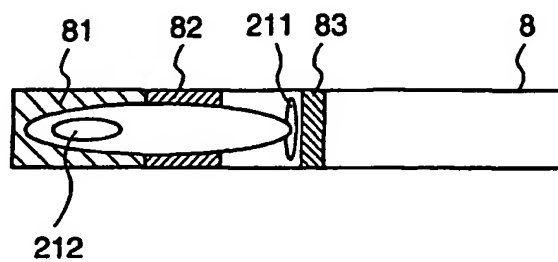


Fig.9 (b)

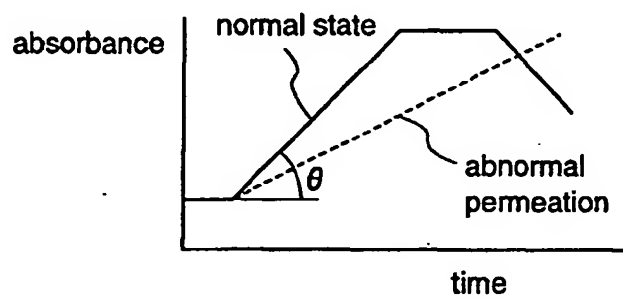




Fig.10 (a)

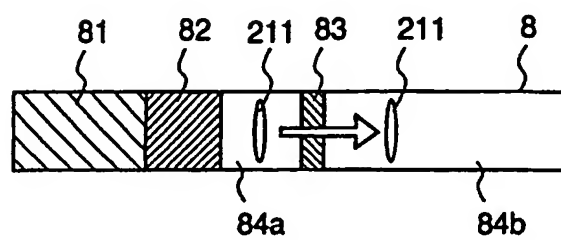


Fig.10 (b)

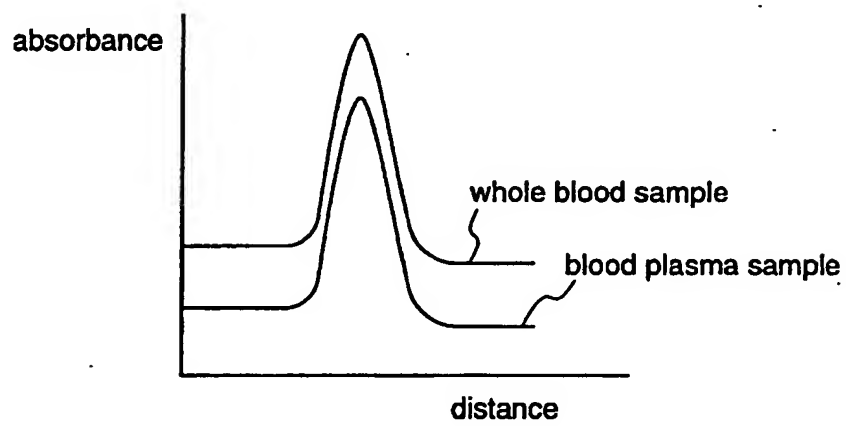


Fig.11 (a)

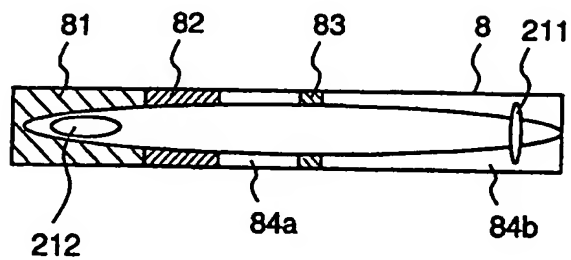


Fig.11 (b)

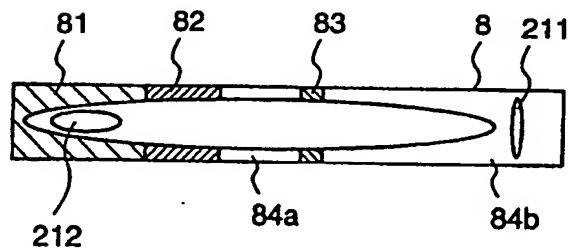


Fig.12 (a)

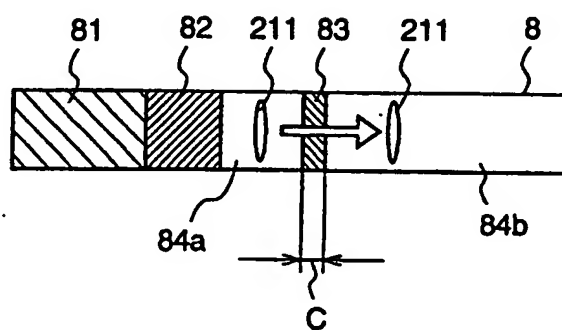


Fig.12 (b)

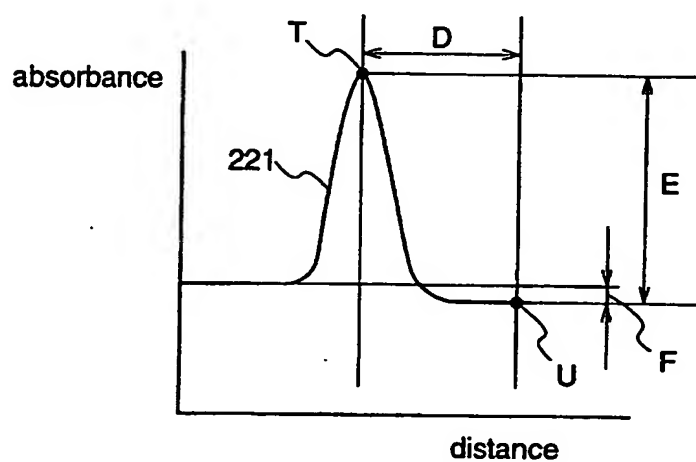


Fig.13 (a)

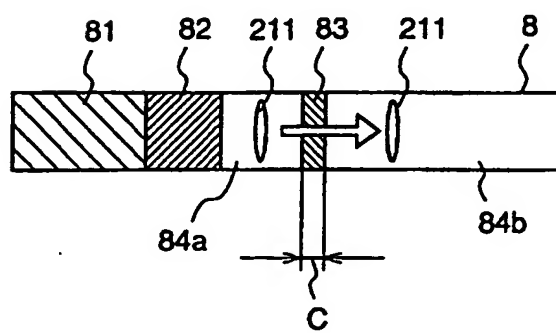


Fig.13 (b)

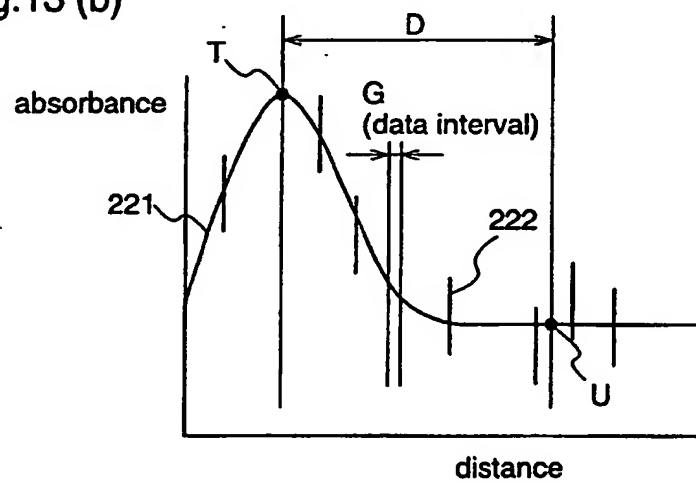


Fig.14 (a)

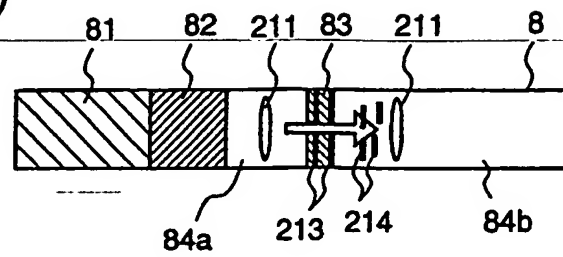


Fig.14 (b)

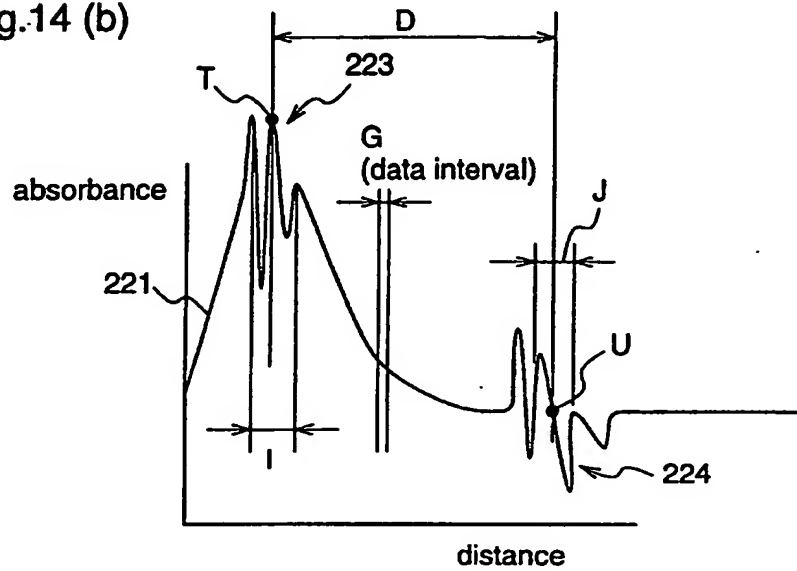


Fig.14 (c)

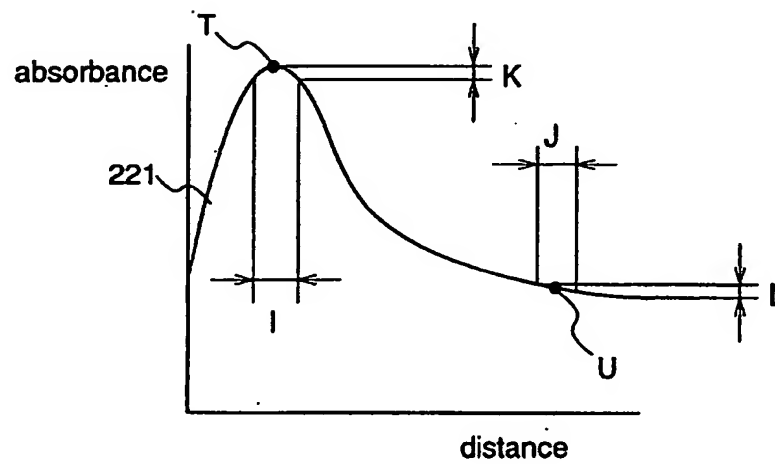


Fig.15

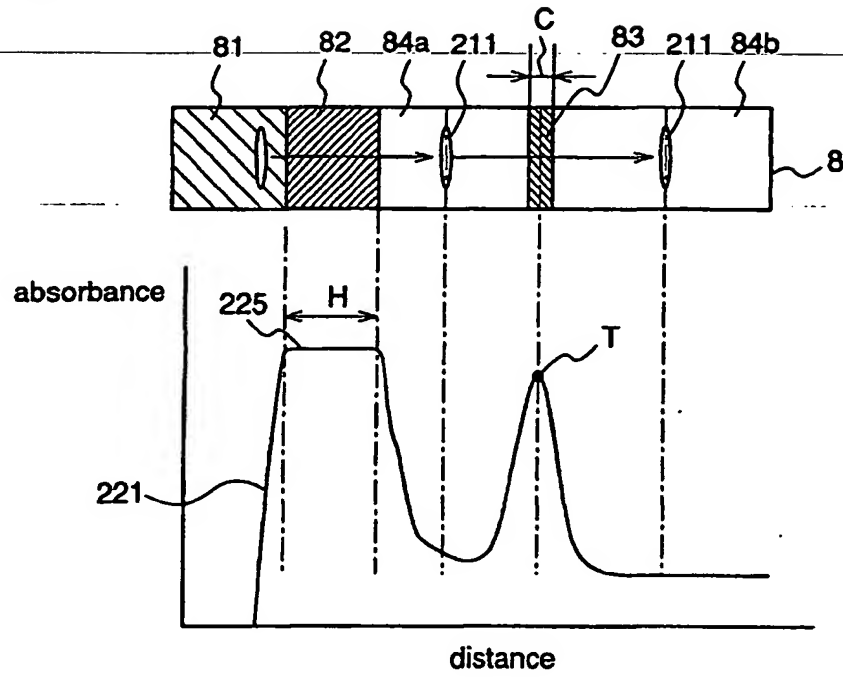


Fig.16

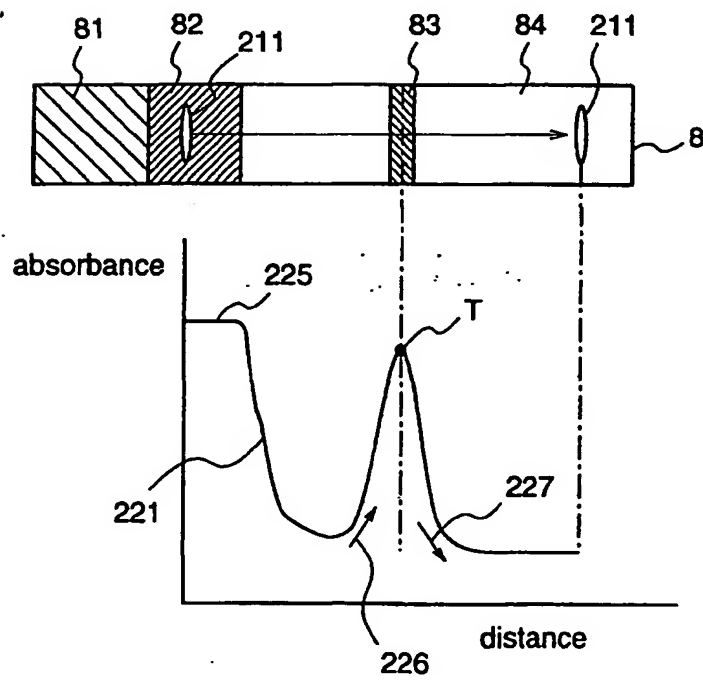


Fig.17

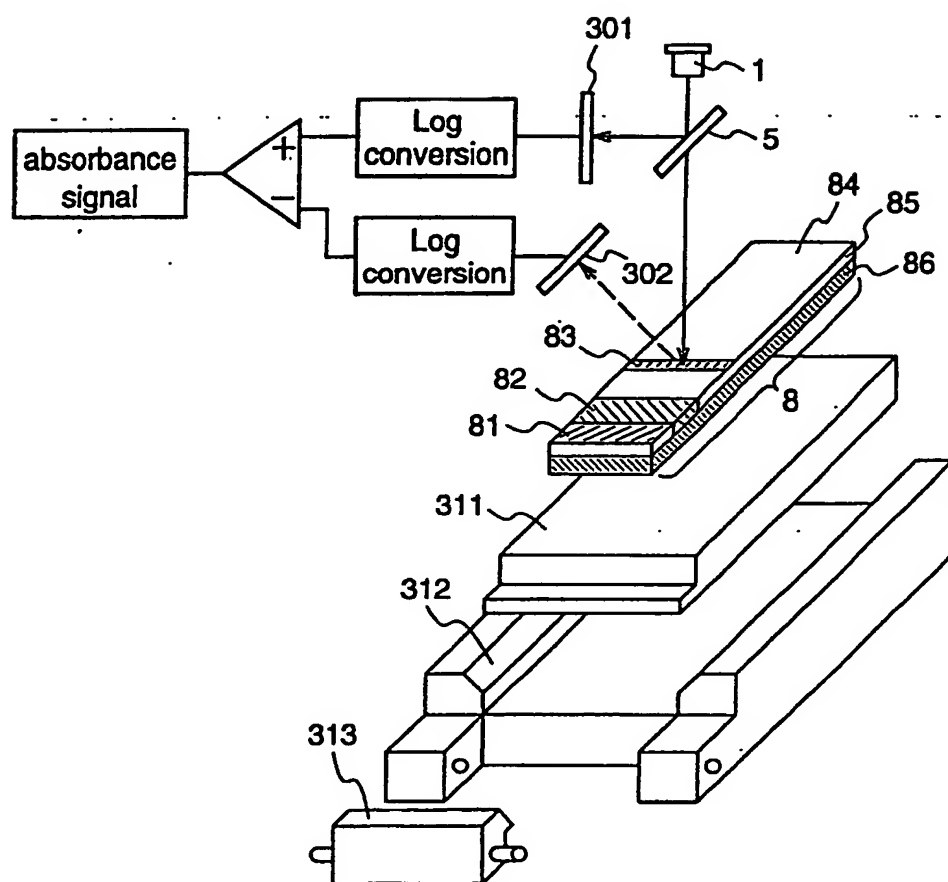




Fig.18

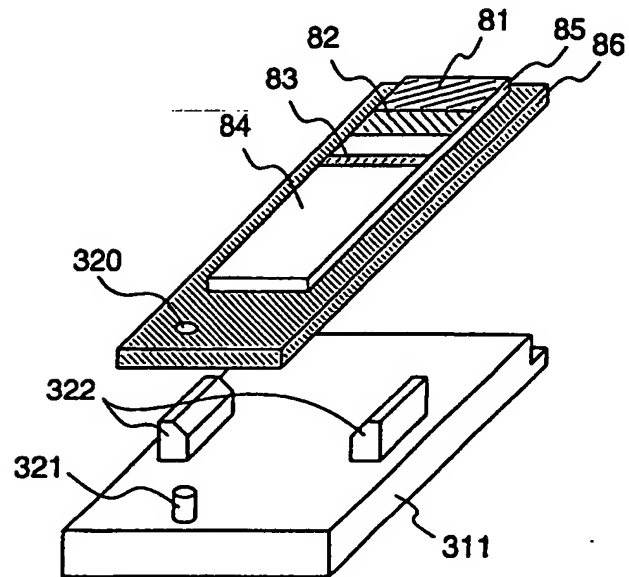
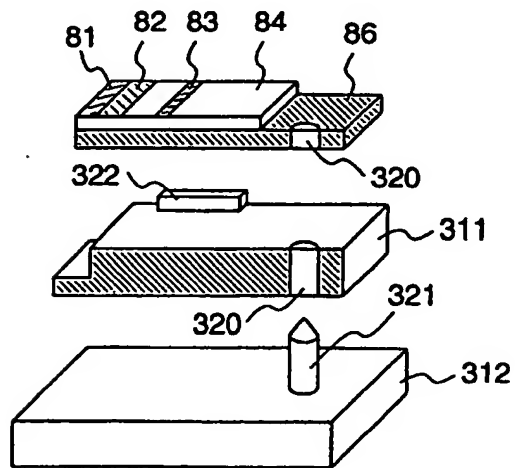
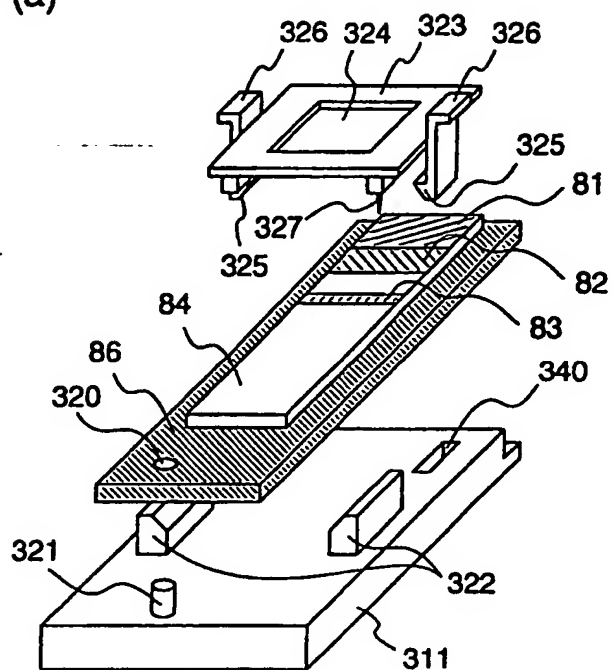


Fig.19



**Fig.20-(a)**



**Fig.20 (b)**

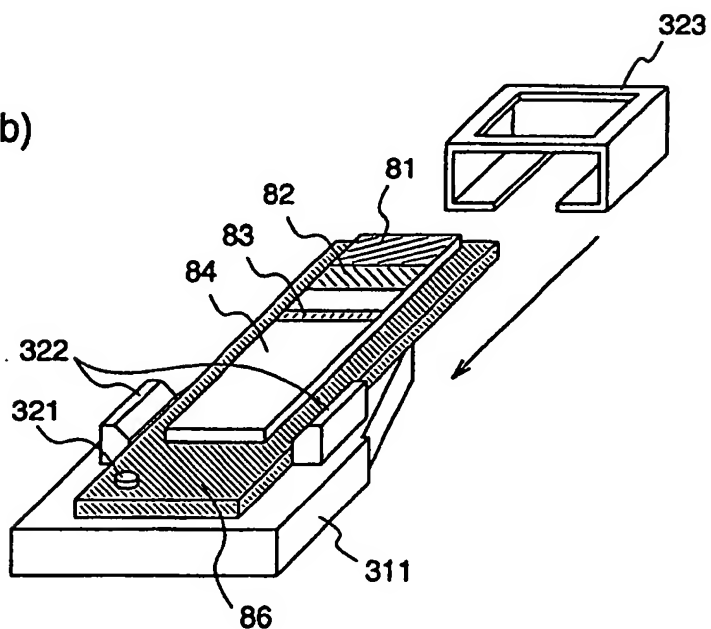


Fig.21

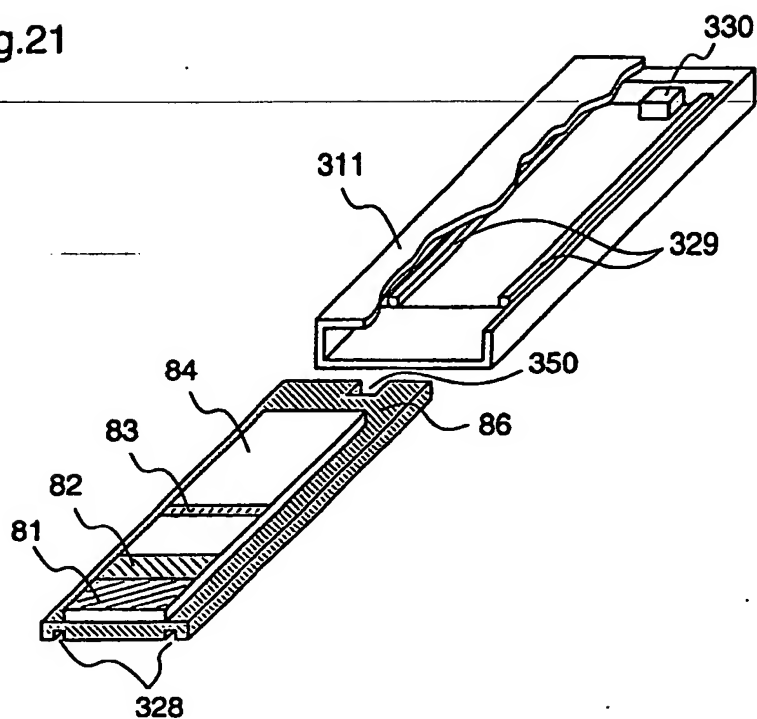


Fig.22 (a)

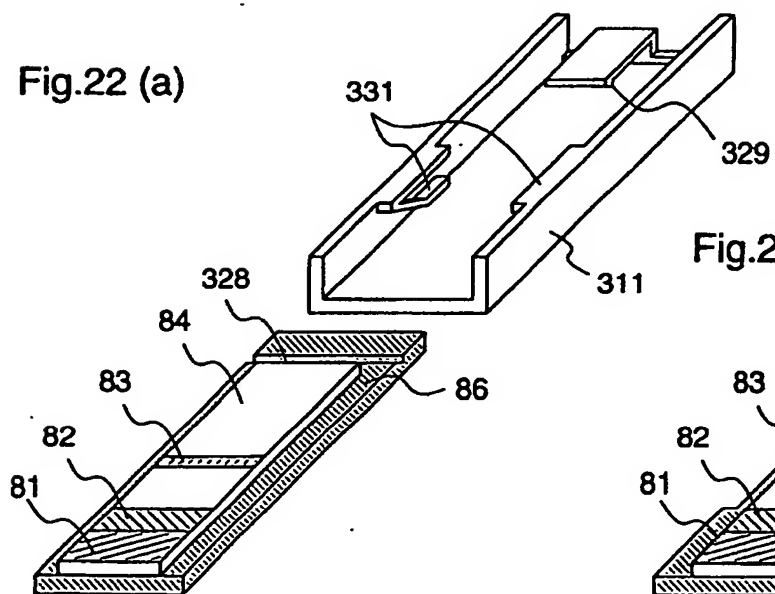


Fig.22 (b)

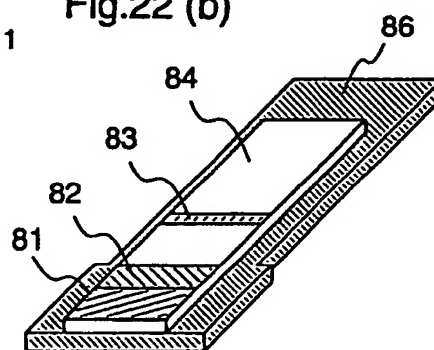


Fig.23

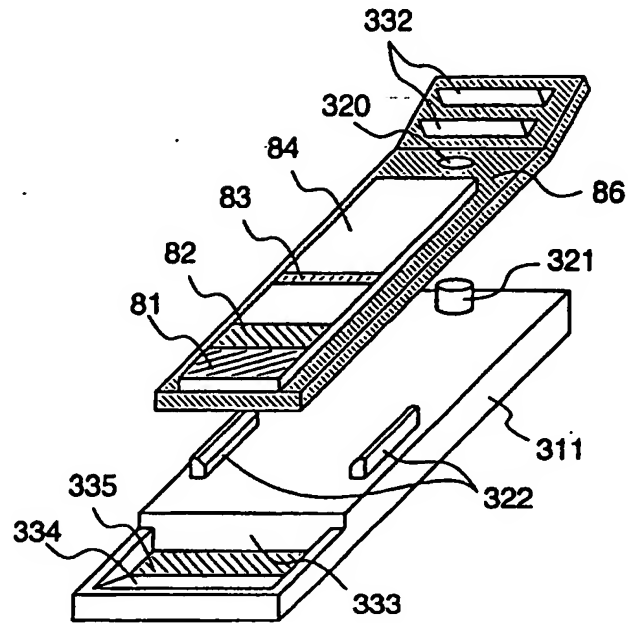


Fig.24

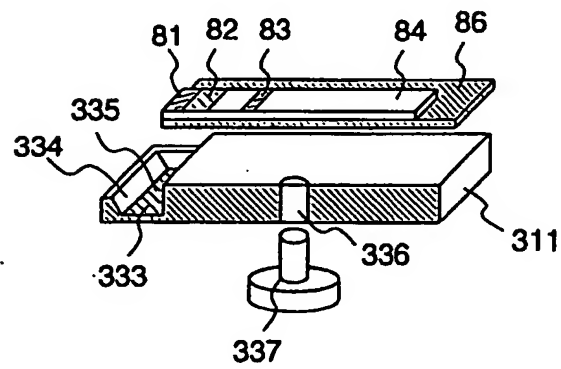


Fig.25 (a)

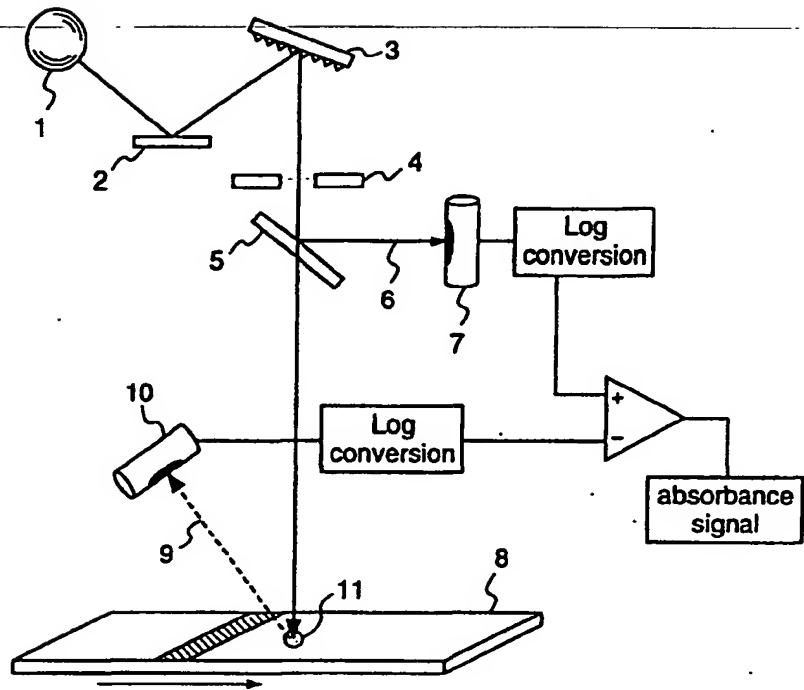


Fig.25 (b)

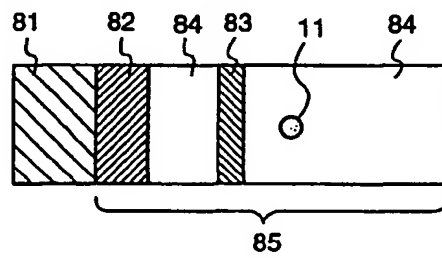
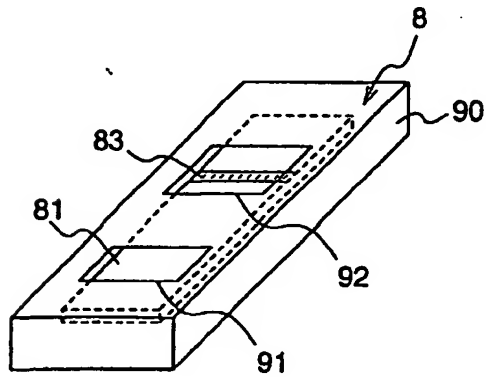


Fig.25 (c)



## INTERNATIONAL SEARCH REPORT

International application No.

PCT/JP01/08314

## A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl.<sup>7</sup> — G01N21/27, — G01N30/90, — G01N33/543

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Int. Cl.<sup>7</sup> G01N21/00-21/65, G01N30/00-30/96, G01N33/48-33/98

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Jitsuyo Shinan Koho	1922-1996	Toroku Jitsuyo Shinan Koho	1994-2001
Kokai Jitsuyo Shinan Koho	1971-2001	Jitsuyo Shinan Toroku Koho	1996-2001

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WPI/L ECLA PATOLIS

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
EX EA	JP 2001-296246 A (Hamamatsu Photonics K.K.), 26 October, 2001 (26.10.01), & WO 01/02990 A	1-3, 5, 8 4, 6, 7, 9-14
X A	JP 11-83745 A (Matsushita Electric Ind. Co., Ltd.), 26 March, 1999 (26.03.99), (Family: none)	15 16-19
A	JP 10-503024 A (Unipath Limited), 17 March, 1998 (17.03.98), & WO 96/09553 A & EP 703454 A & FR 2725024 A & AU 9536522 A & ZA 9508032 A & CZ 9700896 A & BR 9509029 A & ES 2109199 A & HU 77371 A & KR 97706499 A & NZ 293948 A & MX 9702208 A & TW 362008 A & CN 1166875 A	17
A	JP 10-274653 A (Sanko Junyaku K.K.), 13 October, 1998 (13.10.98), (Family: none)	24-26, 29-33

☒ Further documents are listed in the continuation of Box C.☐ See patent family annex.

\* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

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"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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"Z" document member of the same patent family

Date of the actual completion of the international search

18 January, 2002 (18.01.02)

Date of mailing of the international search report

29 January, 2002 (29.01.02)

Name and mailing address of the ISA/  
Japanese Patent Office

Authorized officer

Facsimile No.

Telephone No.

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/JP01/08314

## C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	JP 2000-507353 A (Boehringer Mannheim GmbH), 13 June, 2000 (13.06.00), & DE 19611347 A & WO 97/36168 A & EP 888534 A	34-39
A	JP 7-5110 A (Terametsukusu K.K.), 10 January, 1995 (10.01.95), (Family: none)	34-39
A	JP 10-197510 A (Ina Matallana Kielmann), 31 July, 1998 (31.07.98), & EP 841567 A & DE 19646720 A & US 6130099 A	38, 39
A	JP 5-332918 A (Shimadzu Corporation), 17 December, 1993 (17.12.93), (Family: none)	20-23, 27, 28, 40-66
X	JP 62-76434 A (Shimadzu Corporation), 08 April, 1987 (08.04.87), (Family: none)	1-4, 6
A	JP 61-109015 A (Asahi Optical Co., Ltd.), 27 May, 1986 (27.05.86), (Family: none)	1-14
A	JP 61-283186 A (Hoya Corporation), 13 December, 1986 (13.12.86), (Family: none)	1-14
A	JP 61-61039 A (Shimadzu Corporation), 28 March, 1986 (28.03.86), (Family: none)	1-14

Form PCT/ISA/210 (continuation of second sheet) (July 1992)



## INTERNATIONAL SEARCH REPORT

International application No.

PCT/JP01/08314

**Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)**

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

(See extra sheet.)

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest ☐ The additional search fees were accompanied by the applicant's protest.  
☒ No protest accompanied the payment of additional search fees.

Form PCT/ISA/210 (continuation of first sheet (1)) (July 1992)

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/JP01/08314

Continuation of Box No. II of continuation of first sheet (1)

In claims 1 to 14, a problem to be solved in a device for chromatographic quantitative measurement is to prevent the variation in the coloring of a base portion, and a means for solving the problem is to use a beam having the shape of a rectangle or an ellipse.

In claims 15 to 19, a problem to be solved in a device for chromatographic quantitative measurement is to dispense with the need for manual time control and to identify an used specimen, and a means for solving the problem is to automatically start the measurement of a concentration a predetermined time after the detection of the change of the absorbance of a light to be measured.

In claims 20 to 26, a problem to be solved in a device for chromatographic quantitative measurement is to discriminate a failed specimen caused by clogging or the like, and a means for solving the problem is to measure the speed of developing of a solution to be tested.

In claims 27 and 28, a problem to be solved in a device for chromatographic quantitative measurement is to detect a developing failure of a specimen, and a means for solving the problem is to irradiate the downstream side end of the base portion of the specimen with a light beam and obtain the information on the development in the specimen from optical signals resulting from the irradiation.

In claims 29 to 33, a problem to be solved in a device for chromatographic quantitative measurement is to suppress the effect of a labeled reagent being likely to remain at the downstream side end of the base portion of the specimen on the error in the absorbance measurement, and a means for solving the problem is to regard a signal detected at a position which is downstream from a detecting portion in the developing direction and wherein an optical signal is free from the influence of the detecting portion, as a signal for determining a concentration.

In claims 34 to 37, a problem to be solved in a device for chromatographic quantitative measurement is to prevent the erroneous recognition of the peak position for an absorbance, and a means for solving the problem is to use a specimen having no labeled reagent holding portion when determining a concentration.

In claims 38 and 39, a problem to be solved in a device for chromatographic quantitative measurement is to prevent the erroneous recognition of the peak position for an absorbance, and a means for solving the problem is to determine the extreme value of a detecting signal for the absorbance through the recognition of the rising and falling of the detecting signal.

In claims 40 to 88, a means solving the problem of accurately mounting an immunochromatographic specimen on a device for chromatographic quantitative measurement is to provide a platform for fixing the specimen and a measurement bench for holding the platform.

In the above claims, constituent features comprised of a light source, an adding portion, a labeled reagent holding portion, a base portion, a detecting portion belong to the well-known prior art, as described in the "background technology" section of the present specification. Accordingly, the above-described "means for solving a problem" corresponds to "special technical features" in PCT Rule 13.1.

Accordingly, the above 8 groups of claims have "special technical features" being different from one another, and therefore do not comply with the requirement of unity of invention.